

1 Michael A. Caddell (SBN 249469)
mac@caddellchapman.com
2 Cynthia B. Chapman (SBN 164471)
cbc@caddellchapman.com
3 Amy E. Tabor (SBN 297660)
aet@caddellchapman.com
4 CADDELL & CHAPMAN
P.O. Box 1311
5 Monterey, CA 93942
Tel.: (713) 751-0400
6 Fax: (713) 751-0906

7 *Attorneys for Plaintiff*

8 **IN THE UNITED STATES DISTRICT COURT**
9 **FOR THE EASTERN DISTRICT OF CALIFORNIA**
10 **SACRAMENTO DIVISION**

10 Rio NANCE, individually and on
11 behalf of others similarly situated,

11 *Plaintiff,*

12 v.

13 INTERNATIONAL MEDICAL
14 DEVICES, INC., MENOVA
15 INTERNATIONAL, INC., GESIVA
16 MEDICAL, LLC, JAMES J. ELIST
M. D., a Medical Corporation, and
Dr. James ELIST,

17 *Defendants.*

CASE No. _____

**PLAINTIFF’S ORIGINAL CLASS
ACTION COMPLAINT**

18
19
20
21
22
23
24
25
26
27
28 CASE No. _____

1 Plaintiff Rio Nance files this Original Class Action Complaint against Defendants
2 International Medical Devices, Inc. (“IMD”), Menova International, Inc. (“Menova”), Gesiva
3 Medical, LLC (“Gesiva”), James J. Elist, M.D., a Medical Corporation, and Dr. James Elist and in
4 support of his claims alleges as follows.

5 **I. INTRODUCTION**

6 1. Defendants have jointly developed and marketed the “Penuma” device, a silicone
7 penile implant, as a penis enlargement device. Since at least January 2017, Defendants have
8 engaged in a systematic, coordinated campaign to market Penuma for cosmetic penis enlargement.
9 Their websites and advertisements target men who have healthy, normal bodies but simply want
10 larger penises.

11 2. Dr. James J. Elist has also developed a surgical procedure for implanting the device.
12 He has performed thousands of these procedures, handling patient consults at his clinic in Beverly
13 Hills and performing penile implant surgeries in his operating room at the Beverly Hills South
14 Pacific Surgery Center. Defendants falsely and misleadingly tout the device and procedure as
15 “FDA-cleared,” giving reasonable consumers the false impression that the U.S. Food and Drug
16 Administration (“FDA”) has determined that Penuma is safe and effective for cosmetic penis
17 enlargement procedures in men with healthy, normal bodies.

18 3. Unbeknownst to the men who undergo these procedures, however, Penuma is not safe
19 and effective—nor is it FDA-cleared—for cosmetic penile enlargement. Instead, Penuma is FDA-
20 cleared only “*for use in the cosmetic correction of soft tissue deformities.*” Worse, implantation
21 of the Penuma device not only does not usually result in any lengthening of the penis, it frequently
22 causes scarring, resulting in the penis becoming shorter. In addition, contrary to Defendants’
23 misrepresentations that the procedure is “permanent” and “reversible,” the procedure frequently
24 leads to infections and complications that require removal of the device, which, in turn, causes
25 permanent damage to the penis. Defendants knew these facts at least by 2015, but nevertheless
26 continued to market Penuma as “the first FDA-cleared penile implant for cosmetic enhancement”
27
28

1 and to urge consumers with healthy, normal penises to purchase the Penuma device and procedure
2 to “enhance and enlarge the length, girth, and size of your penis.”

3 4. Defendants profited substantially from these misrepresentations, selling the Penuma
4 device and procedure to thousands of men at a cost of \$15,000–\$20,000 each. Plaintiff accordingly
5 brings this action to recover damages and restitution on behalf of similarly situated consumers and
6 to enjoin Defendants from continuing to falsely advertise and market Penuma as a safe and
7 effective FDA-cleared procedure for cosmetic enhancement of penis size in men with healthy
8 penises.

9 II. PARTIES

10 5. Plaintiff Rio Nance is a resident of Placer County, California.

11 6. Defendant International Medical Devices, Inc. (“IMD”) is a California corporation
12 located at 717 N. Maple Drive, Beverly Hills, CA 90210, in Los Angeles County. It may be served
13 through its registered agent, Jonathan Elist, at the same address.

14 7. Defendant Menova International, Inc., (“Menova”) is a California corporation located
15 at 8500 Wilshire Blvd., Suite 707, Beverly Hills, CA 90211, in Los Angeles County. It may be
16 served through its registered agent, James Elist, at the same address.

17 8. Defendant Gesiva Medical, LLC is a Minnesota limited liability corporation
18 headquartered at 6385 Old Shady Oak Road, Suite 250, Eden Prairie, MN 55344. It may be served
19 through its registered agent, Thomas A. Hopper, at the same address.

20 9. Defendant James J. Elist, M.D., a Medical Corporation, is a California corporation
21 headquartered at 8500 Wilshire Blvd., Suite 707, Beverly Hills, CA 90211. It may be served
22 through its registered agent, James J. Elist, at the same address.

23 10. Defendant Dr. James Elist is an individual residing in Beverly Hills, California.
24 Dr. Elist may be served at 8500 Wilshire Blvd., Suite 707, Beverly Hills, CA 90211.

25 III. JURISDICTION AND VENUE

26 11. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C.
27 § 1332(d) because this is a class action involving over 100 class members in which at least one
28

1 member of the class is a citizen of a State different from at least one Defendant and the matter in
2 controversy exceeds \$5,000,000, exclusive of interests and costs.

3 12. Defendants IMD, Menova, James J. Elist, M.D., a Medical Corporation, and Dr. Elist
4 are subject to general personal jurisdiction in California because IMD, Menova, and James J. Elist,
5 M.D., a Medical Corporation are incorporated in California and maintain their principal places of
6 business in California, and Dr. Elist is a California resident.

7 13. The Court also has specific personal jurisdiction over all Defendants because
8 Defendants purposefully availed themselves of the privilege of doing business in California, and
9 this action arises out of and relates to Defendants' California business activities.

10 14. In addition, all Defendants are subject to specific personal jurisdiction because they
11 intentionally directed their activities into California and caused injuries in California.

12 15. Venue is proper in this district under 28 U.S.C. § 1391(b), because a substantial part
13 of the events or omissions giving rise to Plaintiff's claims occurred in Placer County.

14 16. In addition, venue is also proper in this district pursuant to 28 U.S.C. § 1391(a).
15 Defendants are deemed to reside in this district because their contacts with this district would be
16 sufficient to subject them to personal jurisdiction if this district were a separate state.

17 **IV. JOINT ENTERPRISE LIABILITY**

18 17. Defendants shared a common plan or design for illegally marketing the Penuma device
19 and procedure for cosmetic enlargement of normal penises.

20 18. Each Defendant had knowledge of and agreed to market Penuma for the cosmetic
21 enlargement of normal penises.

22 19. Defendants acted as a joint enterprise with regard to all of the actions alleged in this
23 Complaint.

24 20. Whenever this Complaint makes reference to any act of Defendants, the allegations
25 refer to each of the Defendants, acting individually, and also to all of the Defendants acting jointly.

26 21. All acts of each of the Defendants were ratified and adopted by each of their Co-
27 Defendants.

V. STATEMENT OF FACTS

1
2 22. Before undergoing the Penuma implantation procedure, Plaintiff Rio Nance had a
3 normal, healthy penis. He had no soft tissue deformity of the penis, nor any urological problems
4 of any kind.

5 23. While browsing the Internet, Mr. Nance saw advertisements for the Penuma device
6 and procedure, including Dr. Elist’s website. Mr. Nance saw these advertisements at his home in
7 Rocklin, Placer County, California, where Defendants had directed them in order to induce Placer
8 County residents like Mr. Nance to purchase the Penuma device and undergo the implant
9 procedure.

10 24. Having read Defendants’ advertisements, Mr. Nance reasonably believed that the
11 Penuma device was safe and effective for men like him who had normal penises, but simply wanted
12 their penises to be larger. He further reasonably believed, based on the misrepresentations in
13 Defendants’ advertisements, that the Penuma device had been approved by the FDA, and this
14 belief gave him a sense of comfort that the device was safe and effective. Had Mr. Nance known
15 that Penuma had not in fact been approved or cleared by the FDA for cosmetic penile enlargement
16 in men with normal penises and/or that it was not safe and effective for men with normal, healthy
17 penises, he would not have purchased the Penuma device or procedure.

18 25. Mr. Nance also reasonably believed, based on misrepresentations in Defendants’
19 advertisements, that the Penuma procedure was permanent and completely reversible and that there
20 would be no adverse consequences from removal of the device. Had Mr. Nance known that the
21 Penuma implantation procedure was not permanent and could not be reversed without causing
22 permanent damage to the penis, he would not have purchased the Penuma device or procedure.

23 26. Mr. Nance also reasonably believed, based on misrepresentations in Defendants’
24 advertisements, that the Penuma procedure would result in a natural looking penis. Had Mr. Nance
25 known that the Penuma procedure often results in abnormal and deformed-looking penises, he
26 would not have purchased the Penuma device or procedure.

1 27. Mr. Nance contacted Dr. Elist and scheduled an appointment with him for March of
2 2021. Dr. Elist consulted with Mr. Nance for no more than an hour or two. During this consultation,
3 Mr. Nance filled out a questionnaire and watched a video. At no point did Dr. Elist inform
4 Mr. Nance that Penuma was not safe and effective or not FDA cleared for cosmetic enlargement
5 of normal penises. The next day, Dr. Elist performed surgery to implant the Penuma device in
6 Mr. Nance's body.

7 28. Mr. Nance paid \$16,000 to Dr. James Elist for the device, surgery, and three post-
8 operative care visits.

9 29. Following the surgery, Mr. Nance's penis did not become longer. Instead, the weight
10 of the implant near the glans gave the penis a "cobra-like" appearance that was not aesthetically
11 pleasing. In addition, Mr. Nance suffered complications from the surgery, including scarring.

12 30. Mr. Nance then searched for a reconstructive urological surgeon to remove the
13 Penuma device. He had the device removed by Dr. Joel Gelman, a reconstructive urological
14 surgeon at the University of California at Irvine. Following the removal, Mr. Nance has continued
15 to suffer complications, including retraction, loss of sensation, and scarring. These complications
16 caused Mr. Nance significant pain and mental anguish.

17 31. Mr. Nance's experience led him to conclude that the Penuma device and procedure
18 have no value and is not safe or effective for healthy men with normal penises, many of whom had
19 been and would continue to be misled by Defendants' misrepresentations to pay thousands of
20 dollars for a device and surgery that have no value. He further understood that many of these men
21 were unlikely to be able to secure legal representation on their own to pursue their claims against
22 Defendants. He therefore files this action on his own behalf and on behalf of similarly situated
23 persons.

1 **VI. CLASS ALLEGATIONS**

2 **A. Defendants jointly developed and marketed the Penuma device and implantation**
3 **procedure.**

4 32. Promoting himself as the “Thomas Edison of penis surgeries,” Dr. Elist received a
5 patent on the device that was later to be named “Penuma” in 2002. He submitted an application
6 for FDA clearance in 2004, analogizing the device to a silicone implant used for reconstructive
7 surgery of the ear, nose, and throat. In this and all subsequent FDA clearance applications,
8 Defendants specifically limited the intended use for the device to the “correction of soft-tissue
9 deformities.”

10 33. Beginning in 2004, Dr. Elist created National Medical Devices, Inc. (“NMD”)—the
11 predecessor of Defendant IMD—to manufacture the device and serve as its exclusive distributor.
12 Through NMD, Dr. Elist began marketing the device and offering surgical services to implant the
13 device from his clinic in Beverly Hills.

14 34. In 2013, Dr. Elist renamed NMD “International Medical Devices, Inc.” Dr. Elist is the
15 President of IMD and owns 100% of IMD. His son, Jonathan Elist, is IMD’s chief executive
16 officer.

17 35. Dr. Elist subsequently created Menova to hold the intellectual property associated with
18 his silicone penile implant device. On January 10, 2016, Menova applied for trademark registration
19 for the “Penuma” mark with the United States Patent and Trademark Office (“USPTO”). On
20 September 20, 2016, the USPTO issued a trademark for “Penuma.” Since that time, Menova has
21 owned the Penuma trademark and all intellectual property rights associated with the device.
22 Dr. Elist is the president of Menova and owns 100% of Menova.

23 36. In May 2017, IMD entered into an agreement with Gesiva for the distribution of
24 Penuma devices. Menova and Dr. Elist have authorized IMD and Gesiva to contract with
25 approximately 12 urologists around the United States to perform hundreds of Penuma implantation
26 procedures and use the Penuma trademark. Dr. Elist personally trains all urologists authorized to
27 implant the Penuma.

1 37. Penuma’s advertising claims that the device will make patients’ penises longer. That
2 is false. There is no evidence that the Penuma device makes patients’ non-erect penises
3 longer. Worse, Penuma’s design results in patients’ erect penises becoming *shorter* in most cases
4 and in many cases disfigured. Defendants have known about these complications for at least over
5 half a decade. In a 2015 post titled “My Elist Implant Experience,” a former patient detailed his
6 effort at seeking a refund from Dr. Elist after his “erect length” shrank between 1–1.5” post-
7 surgery. He received no refund. Similar patient complaints were posted on the internet during the
8 same timeframe. Instead of correcting his false and misleading claims, Dr. Elist responded to these
9 complaints with cease-and-desist letters. Patient concerns regarding the Penuma were echoed by
10 practitioners and academics as well. For example, a 2018 article published in the Journal of Sexual
11 Medicine titled “Complications of Genital Enlargement Surgery” identified “major penile
12 shortening and disabling curvature” as Penuma complications.

13 38. Instead of disclosing these material risks, Defendants directed consumers to a self-
14 authored, and self-serving, Elist study from 2018 (“*A Single-Surgeon Retrospective and*
15 *Preliminary Evaluation of the Safety and Effectiveness of the Penuma Silicone Sleeve Implant for*
16 *Elective Cosmetic Correction of the Flaccid Penis*”) throughout their marketing. This study,
17 however, was not conducted according to scientific standards, and its unreliability has been noted
18 in the medical literature. Drs. Kapadia, Olson, and Furr, among others, concluded that Dr. Elist’s
19 study failed to consider “long-term sequelae of such adverse events and implant removal, such as
20 penile shortening, fibrosis, and sexual dysfunction.”¹ Because “the infection and explantation rate
21 may be higher than reported in this retrospective study due to incomplete cohort response to
22 surveys,”² several urologists have cautioned that “rigorous investigation with accurate reporting
23 of complications should be mandated before more men take on the physical, mental, and
24

25 _____
26 ¹ Hehemann, *Penile Girth Enlargement Strategies: What’s the Evidence?*, 7 SEXUAL MEDICINE
REVIEW 535–547, 542 (2019).

27 ² Olson, *Management of infected Penuma implant: Case Report*, 6 J. CASE REPORTS AND IMAGES
28 IN UROLOGY 1–3, 2 (2021).

1 significant financial burden associated with subcutaneous silicone penile implants.”³ Defendants’
2 marketing failed to disclose and actively concealed these facts from consumers.

3 **B. Penuma has been FDA-cleared only for cosmetic correction of deformities.**

4 39. Because Penuma is a medical device, it is subject to the Medical Device Amendments
5 of 1976 (“MDA”) to the Food, Drug, and Cosmetic Act (“FDCA”). The MDA established three
6 “classes” of medical devices: Class I, II, and III. “The three classes are based on the degree of
7 control necessary to assure that the various types of devices are safe and effective.”⁴ A post-1976
8 medical device is automatically placed into Class III and is subject to premarket approval (“PMA”)
9 requirements, including the FDA’s independent “scientific review to ensure the safety and
10 effectiveness” of the device. The PMA process is highly rigorous, requiring manufacturers to
11 submit detailed information regarding the safety and effectiveness of their devices. The FDA
12 spends an average of 1,200 hours reviewing each submission.

13 40. Devices that were on the market before the MDA was enacted, however, are
14 grandfathered in and are not required to go through the PMA process. Manufacturers seeking a
15 less stringent review can thus avoid the FDA’s thorough, scientific PMA process by showing that
16 their devices are “substantially equivalent” to devices that were already on the market in 1976.
17 This less rigorous “clearance” to market a device based on substantial equivalency to a pre-1976
18 device is known as FDCA Section 510(k) Premarket Notification process (the “510(k) clearance”
19 process).

20 41. Section 510(k) clearance allows device manufacturers, like Defendants, to submit a
21 relatively short “summary” to the FDA describing how their medical devices are “substantially
22 equivalent” to a pre-1976 device (the “predicate device”). The significant evidence needed to
23 obtain full FDA approval of a medical device is not required when a medical device manufacturer
24 instead applies for FDA “clearance” via the 510(k) process.

25
26 ³ Hehemann at 543.

27 ⁴ U.S. Food and Drug Administration, PMA Approvals, *available at* <https://www.fda.gov/medical-devices/device-approvals-denials-and-clearances/pma-approvals> (last visited August 9, 2021).
28

1 42. If the FDA determines that a device is “substantially equivalent” for the indicated uses
2 to a pre-1976 device, manufacturers may obtain a fast-tracked 510(k) clearance to market the
3 device while avoiding rigorous PMA testing for safety and effectiveness. 510(k) clearance is
4 limited, however, to authorization to market the device *for the indicated uses*. In submitting a
5 510(k) clearance application, the manufacturer must identify the device’s intended use. This
6 intended use must match the intended use of the pre-1976 device to which the manufacturer claims
7 “substantial equivalency.” *See* 21 C.F.R. § 807.81(a)(ii). If a major change or modification of the
8 intended use is identified, the 510(k) clearance process is unavailable, and the device must go
9 through the full PMA process instead. *Id.*

10 43. On or about September 1, 2004, National Medical Devices, Inc. (the predecessor to
11 IMD) submitted its “Silicone Block” for Section 510(k) premarket notification of intent to market
12 the device. National Medical Devices, Inc. submitted that the implant was substantially equivalent
13 to an “ear, nose and throat synthetic polymer material,” which is regulated as a Class II Device
14 under 21 CFR § 874.3620, which provides:

15 Ear, nose, and throat synthetic polymer material is a device material
16 that is intended to be implanted for use as a space-occupying
17 substance in the reconstructive surgery of the head and neck. The
18 device is used, for example, in augmentation rhinoplasty and in
19 tissue defect closures in the esophagus. The device is shaped and
formed by the surgeon to conform to the patient’s needs. This
generic type of device is made of material such as polyamide mesh
or foil and porous polyethylene.

20 On October 25, 2004, the FDA granted 510(k) clearance to the Silicone Block that “is intended
21 *for use in the cosmetic correction of soft tissue deformities*, and is contoured at the surgeon’s
22 discretion to create a custom implant to aid in the reconstruction process.” (Emphasis added.)

23 44. Due to certain design changes to Dr. Elist’s penile implant device, on December 20,
24 2016, Defendants caused International Medical Devices, Inc. (“IMD”)—the successor to National
25 Medical Devices—to submit a second Section 510(k) premarket notification for a “Pre-Formed
26 Penile Silicone Block.” This application identified National Medical Device’s Silicone Block,
27 which had been cleared in 2004 based on its asserted similarity to an ear, nose, and throat
28

1 reconstructive implant, as the predicate device to which IMD’s Pre-Formed Penile Silicone Block
2 was “substantially equivalent.” The FDA granted 510(k) clearance on February 1, 2017, describing
3 the “Indications for Use” as follows: “Pre-Formed Penile Silicone Block is intended for use in the
4 cosmetic correction of soft tissue deformities, and is contoured at the surgeon’s discretion to create
5 a custom implant.” Following certain additional design changes, on December 19, 2018, IMD
6 again applied for Section 510(k) premarket notification. Again, the FDA’s 510(k) clearance, dated
7 January 23, 2019, identified the exact same “Indications for Use,” *i.e.*, limited to “***use in the***
8 ***cosmetic correction of soft tissue deformities.***”

9 45. Despite these clear limitations to the uses for which the device is FDA-cleared,
10 Defendants regularly misrepresent Penuma as safe and effective and FDA-cleared for cosmetic
11 enlargement of normal penises.

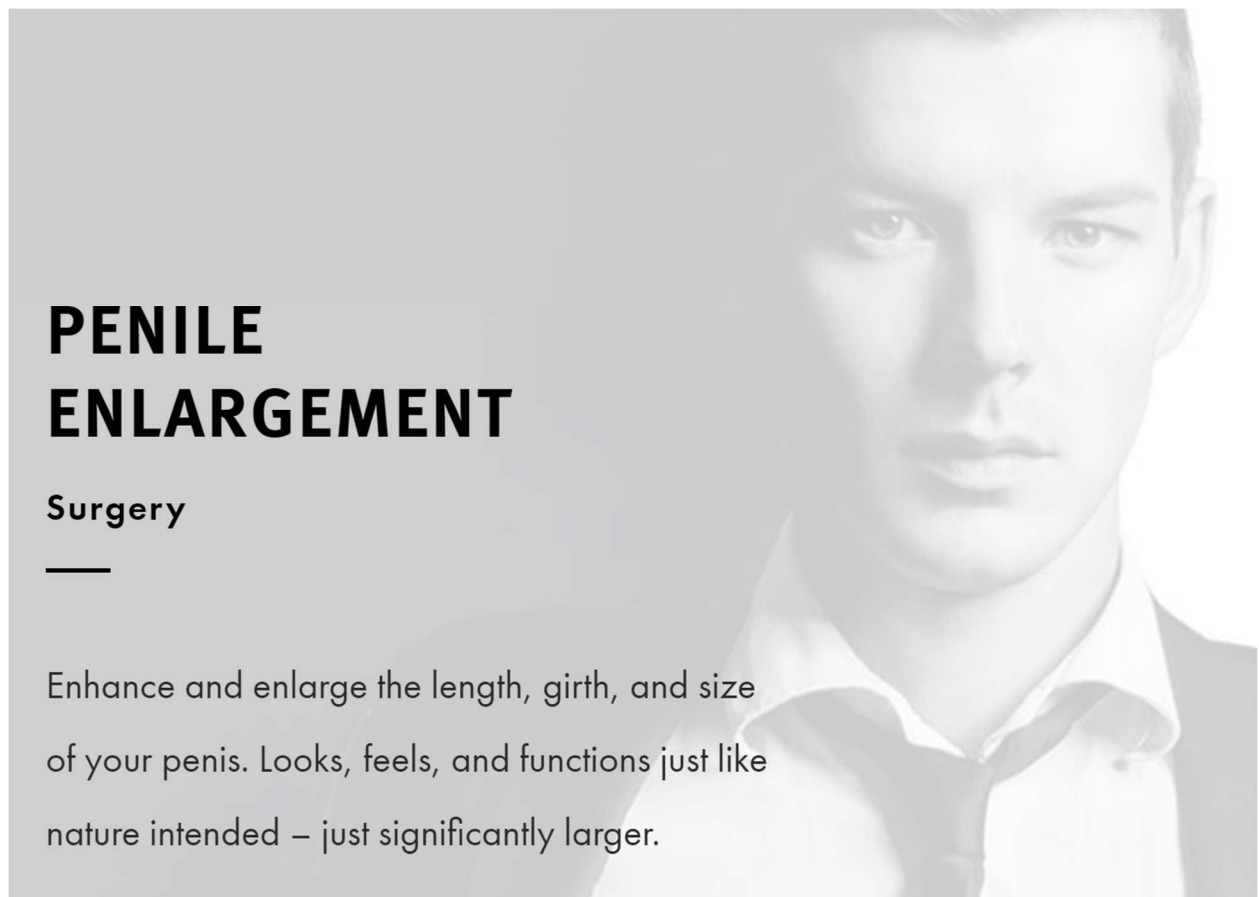
12 46. Penile soft tissue deformities, including Peyronie’s disease, congenital micropenis,
13 and congenital ventral curvature, are serious medical conditions that can cause significant pain and
14 prevent men from having sexual intercourse, in addition to shortening the penis. These deformities
15 are rare, with Peyronie’s affecting approximately 10% of men over 40, and congenital ventral
16 curvature and congenital micropenis affecting less than 1% and 0.6% of the population,
17 respectively. The market for a device limited to “use in the cosmetic correction of soft tissue
18 deformities” is therefore relatively small.

19 47. A much larger market, however, exists for the cosmetic enhancement of penis size in
20 men with normal penises. Many healthy men with normal penises desire larger penises for
21 cosmetic reasons or to improve their sense of sexual self-confidence. This market, for which
22 Penuma is ***neither safe and effective nor FDA-cleared***, is potentially worth millions.

23 48. Seeking to capitalize on this larger, more lucrative market, Defendants regularly
24 falsely and misleadingly represent that Penuma is safe, effective, and FDA-cleared for “cosmetic
25 enhancement” and advertise it as a penis enlargement device. In fact, Penuma is not safe and
26 effective for use as a penis enlargement device and has not been FDA-cleared for such use.
27 Defendants regularly fail to disclose and actively conceal these facts from consumers.

1 49. Defendants market Penuma on Dr. Elist’s personal website, <https://www.drelist.com/>,
2 as well as at <http://www.penuma.com>. Defendants advertise Penuma at www.penuma.com as a
3 “Penis Enhancement Implant for Men.” The same website claims that Penuma is “the first FDA-
4 cleared penile implant for cosmetic enhancement.” The website also claims that Penuma will cause
5 “[s]ignificant, permanent cosmetic enhancements to the penis.” The website is intended to and
6 does cause a reasonable consumer to believe, falsely, that Penuma is safe and effective and FDA-
7 cleared for cosmetic enlargement of normal penises in healthy men. Nothing on the website
8 discloses that Penuma is FDA-cleared only for use in the cosmetic correction of soft tissue
9 deformities. Defendants have made these material misrepresentations and omissions consistently
10 since at least 2017, and they continue to do so as of the date of the filing of this Complaint.

11 50. Defendants similarly market Penuma on Dr. Elist’s website as “the first FDA-cleared
12 penile implant for cosmetic enhancement.” The website’s tab identifies Dr. Elist as performing



28 Figure 1: www.drelist.com

1 “Penile Enlargement Surgery” and urges men to “Enhance and enlarge the length, girth, and size
2 of your penis.”

3
4 51. Gesiva’s website similarly misrepresents that Penuma is “FDA-cleared for cosmetic
5 enhancement.” See Gesiva Medical, Penis Enlargement Surgery: Cost and Risk, *available at*
6 <https://www.gesiva.com/2019/12/penis-enlargement-surgery-cost-and-risk/>.

7 52. Defendants have been making these same misrepresentations for over half a decade,
8 at least:

9 **2017:**

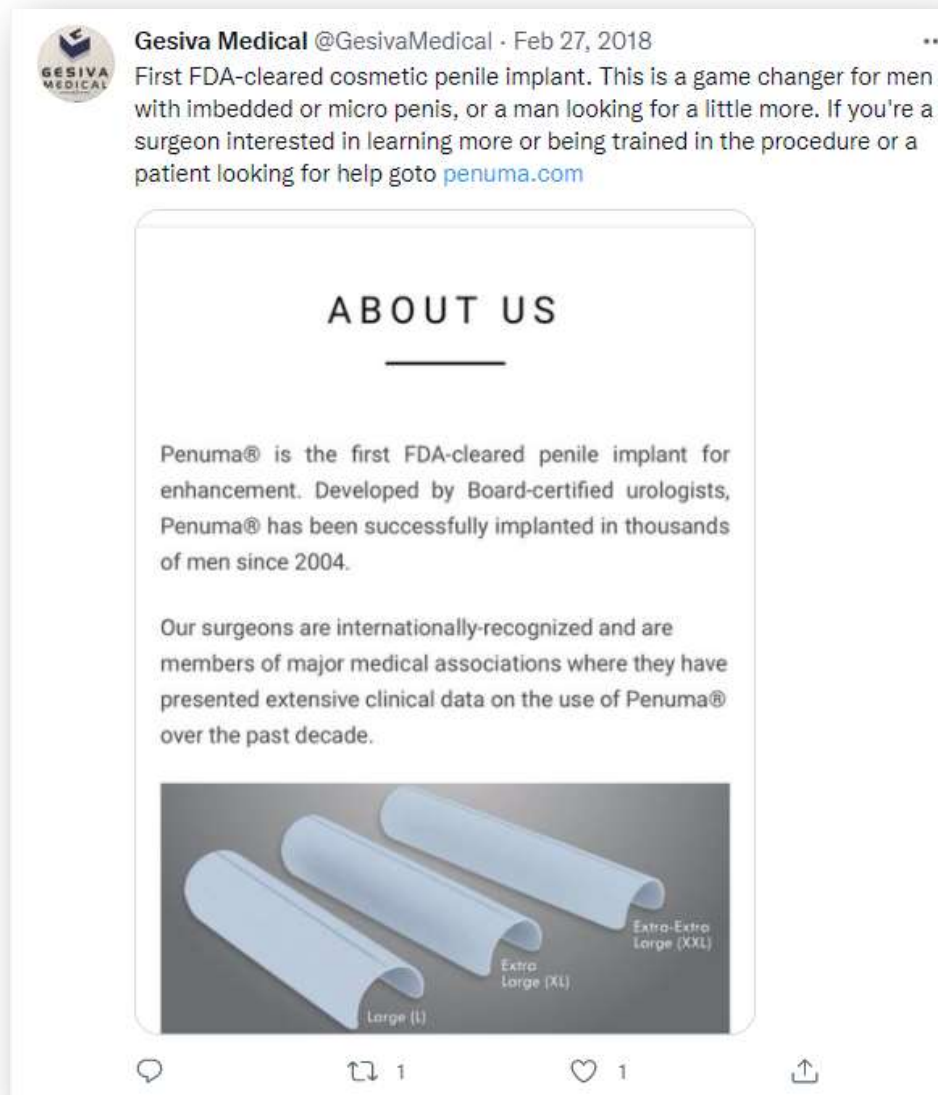


Figure 2: <https://twitter.com/gesivamedical>

1 **2018**

2

3 **ADVANTAGES**

4

5

6 PENUMA® IS THE FIRST FDA-CLEARED PENILE IMPLANT FOR ENHANCEMENT.

7 KEY IMPLANT AND OPERATIVE/POST-OPERATIVE FEATURES INCLUDE:

8

Implant Features	Operative and Post-Operative Features
> Significant, permanent enhancements to the penis	> Short, outpatient procedure (i.e., 45-60 minutes)
> Natural Looking	> No incisions or scar formation on the penis
> Reversible	Short recovery time (i.e., patient return to routine daily activities within 2-4 days)
> No interference with penile function	> Strong track record of effectiveness and patient and partner satisfaction
> No blockage of, or interference with, the urethra (e.g., for future cystoscopy)	Low adverse event rate on par with silicone implants for other anatomical regions (e.g., calf, buttock, chin)
> Implant is contoured by the surgeon to your individual size	Can be performed before or after a penile prosthesis procedure for the treatment of erectile dysfunction
> Manufactured in the US by an ISO-certified, FDA-registered facility	

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23 Figure 3: <https://web.archive.org/web/20180626111235/http://www.penuma.com/>

FEATURES OF THE PENUMA[®] IMPLANT

The Penuma[®] Implant is designed to offer natural and aesthetic looking enhancements. This implant is done exclusively by Dr. Elist and on a limited basis by a select group of top surgeons across the US. The features of the Penuma[®] Implant include:

- Enhanced and natural feel and appearance
- Potential increases in penis width and flaccid length
- Permanent results
- Reversible at any time
- No interference with normal penis function
- Completely customizable implant to perfectly suit your needs
- Made of medical grade silicone, that is soft and feels natural but does not have a gel core (like many breast implants)



Figure 4: <https://web.archive.org/web/20201001025806/https://www.drelist.com/penile-procedures/penuma-implant/>

2019:

A black and white advertisement for penile enlargement surgery. On the right side, there is a portrait of a young man with dark hair, wearing a dark suit jacket, a white dress shirt, and a dark tie. He has a serious expression. On the left side, there is text:

**PENILE
ENLARGEMENT**

Surgery

—

Enhance and enlarge the length, girth, and size of your penis. Looks, feels, and functions just like nature intended – just significantly larger.

[Learn More](#) | [Gallery](#)

Figure 5: <https://web.archive.org/web/20190714095548/https://www.drelist.com/>

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

ADVANTAGES

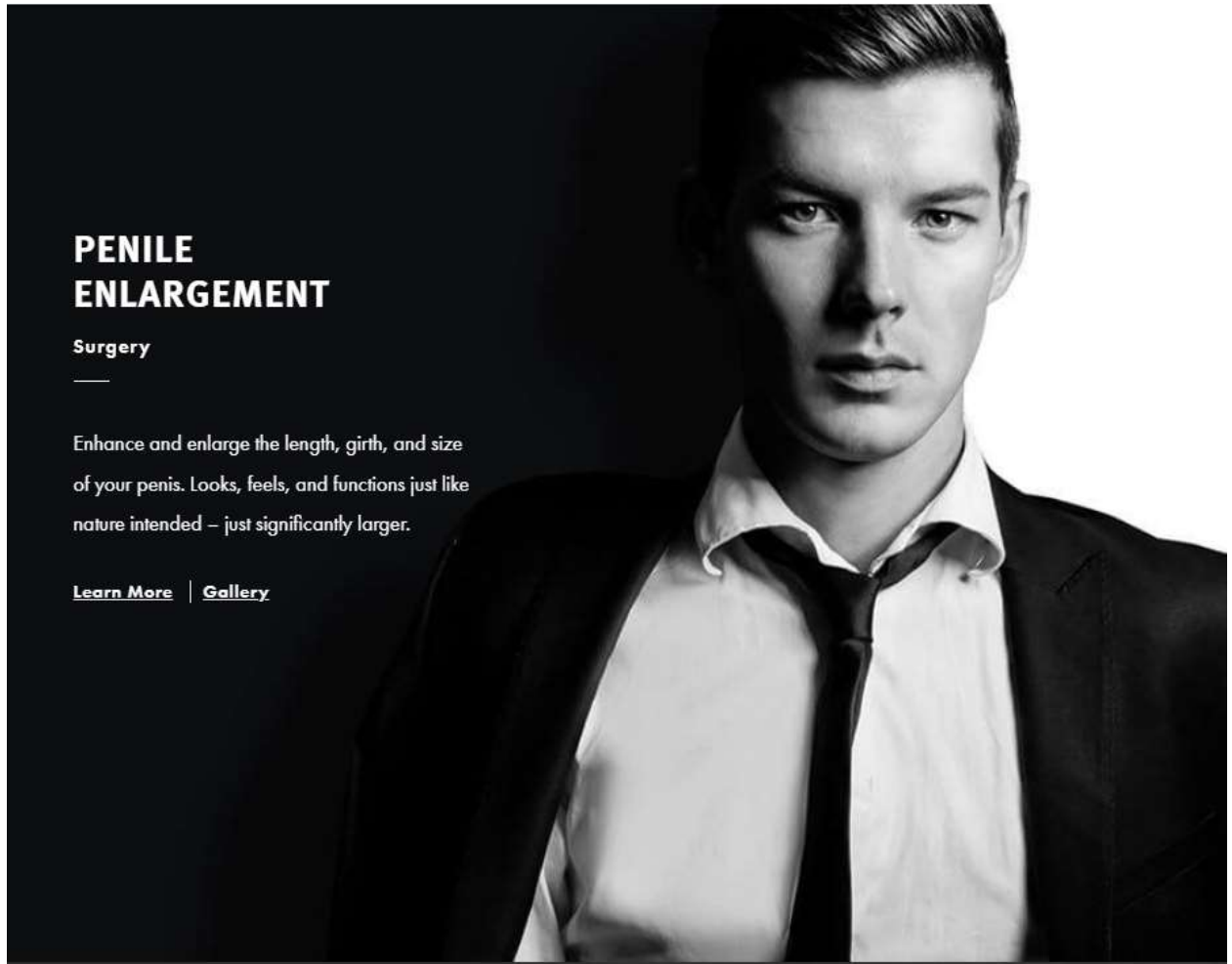
PENUMA® IS THE FIRST 510(K)-CLEARED PENILE IMPLANT FOR COSMETIC ENHANCEMENT.

KEY IMPLANT AND OPERATIVE/POST-OPERATIVE FEATURES INCLUDE:

Implant Features	Operative and Post-Operative Features
> Significant, permanent cosmetic enhancements to the penis	> Short, outpatient procedure (i.e., 45-60 minutes)
> Natural Looking	> No incisions or scar formation on the penis
> Reversible	> Short recovery time (i.e., patient return to routine daily activities within 2-4 days)
> No interference with penile function	> Strong track record of effectiveness and patient and partner satisfaction
> No blockage of, or interference with, the urethra (e.g., for future cystoscopy)	> Low adverse event rate on par with silicone implants for other anatomical regions (e.g., calf, buttock, chin)
> Implant is contoured by the surgeon to your individual size	> Can be performed before or after a penile prosthesis procedure for the treatment of erectile dysfunction
> Manufactured in the US by an ISO-certified, FDA-registered facility	

Figure 6: <https://web.archive.org/web/20190609121832/https://www.penuma.com/>

1 **2020:**



18 Figure 7: <https://web.archive.org/web/20200701020552/https://www.drelist.com/>

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

ADVANTAGES

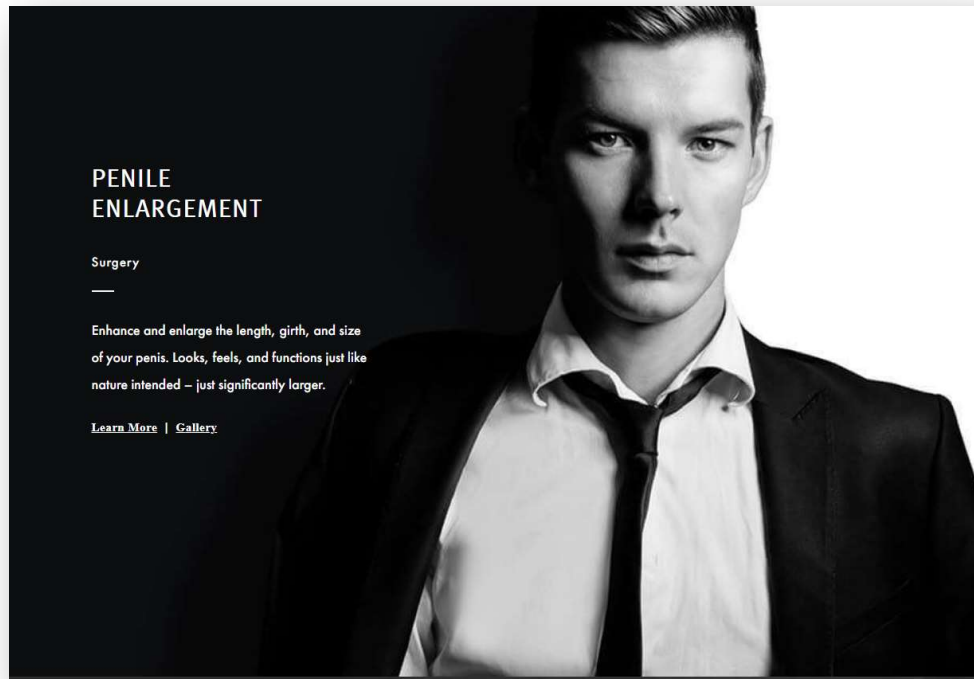
PENUMA® IS THE FIRST 510(K)-CLEARED PENILE IMPLANT FOR COSMETIC ENHANCEMENT.

KEY IMPLANT AND OPERATIVE/POST-OPERATIVE FEATURES INCLUDE:

Implant Features	Operative and Post-Operative Features
> Significant, permanent cosmetic enhancements to the penis	> Short, outpatient procedure (i.e., 45-60 minutes)
> Natural Looking	> No incisions or scar formation on the penis
> Reversible	> Short recovery time (i.e., patient return to routine daily activities within 2-4 days)
> No interference with penile function	> Strong track record of effectiveness and patient and partner satisfaction
> No blockage of, or interference with, the urethra (e.g., for future cystoscopy)	> Low adverse event rate on par with silicone implants for other anatomical regions (e.g., calf, buttock, chin)
> Implant is contoured by the surgeon to your individual size	> Can be performed before or after a penile prosthesis procedure for the treatment of erectile dysfunction
> Manufactured in the US by an ISO-certified, FDA-registered facility	

Figure 8: <https://web.archive.org/web/20190609121832/https://www.penuma.com/>

1 **Today:**



14 Figure 9: <https://www.drelist.com/>

15

16

17

18

19

20

21

22

23

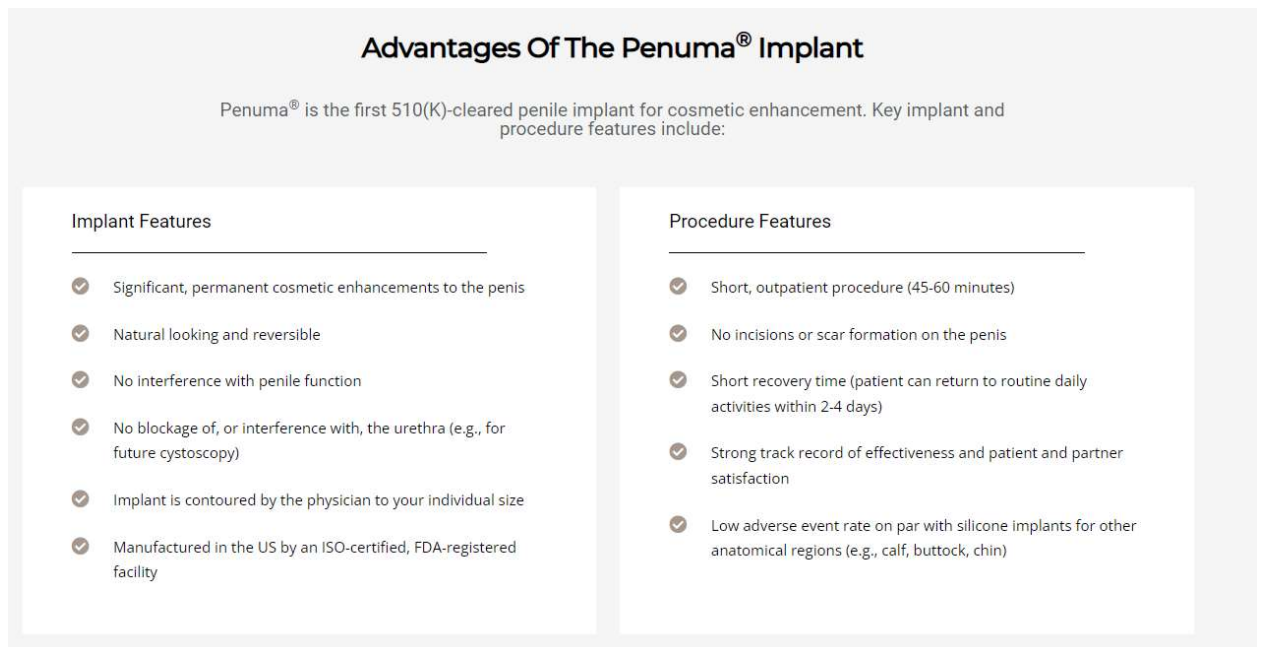
24

25

26

27

28



Advantages Of The Penuma® Implant

Penuma® is the first 510(K)-cleared penile implant for cosmetic enhancement. Key implant and procedure features include:

Implant Features	Procedure Features
<ul style="list-style-type: none">✓ Significant, permanent cosmetic enhancements to the penis✓ Natural looking and reversible✓ No interference with penile function✓ No blockage of, or interference with, the urethra (e.g., for future cystoscopy)✓ Implant is contoured by the physician to your individual size✓ Manufactured in the US by an ISO-certified, FDA-registered facility	<ul style="list-style-type: none">✓ Short, outpatient procedure (45-60 minutes)✓ No incisions or scar formation on the penis✓ Short recovery time (patient can return to routine daily activities within 2-4 days)✓ Strong track record of effectiveness and patient and partner satisfaction✓ Low adverse event rate on par with silicone implants for other anatomical regions (e.g., calf, buttock, chin)

Figure 10: <https://penuma.com/>

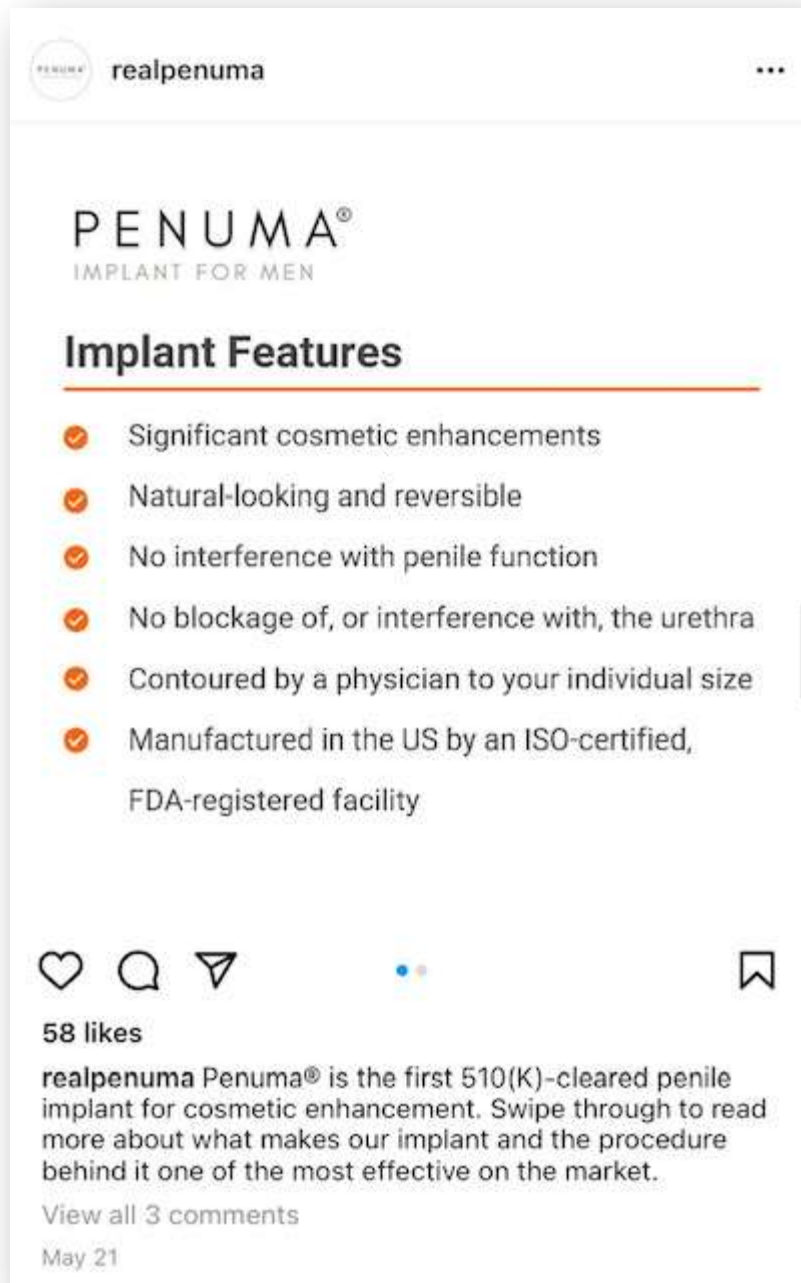


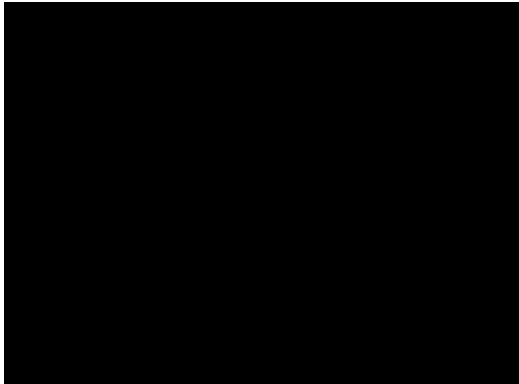
Figure 11: <https://www.instagram.com/realpenuma/?hl=en>

1
2 53. The websites are intended to and do cause a reasonable consumer to believe, falsely,
3 that Penuma is safe and effective and FDA-cleared for cosmetic enlargement of normal penises in
4 healthy men. Nothing on the websites discloses that Penuma is FDA-cleared only for use in the
5 cosmetic correction of soft tissue deformities, that it is not effective to enhance the appearance of
6 normal penises, or that it frequently causes complications that require the implant to be removed,
7 causing permanent damage to the penis.

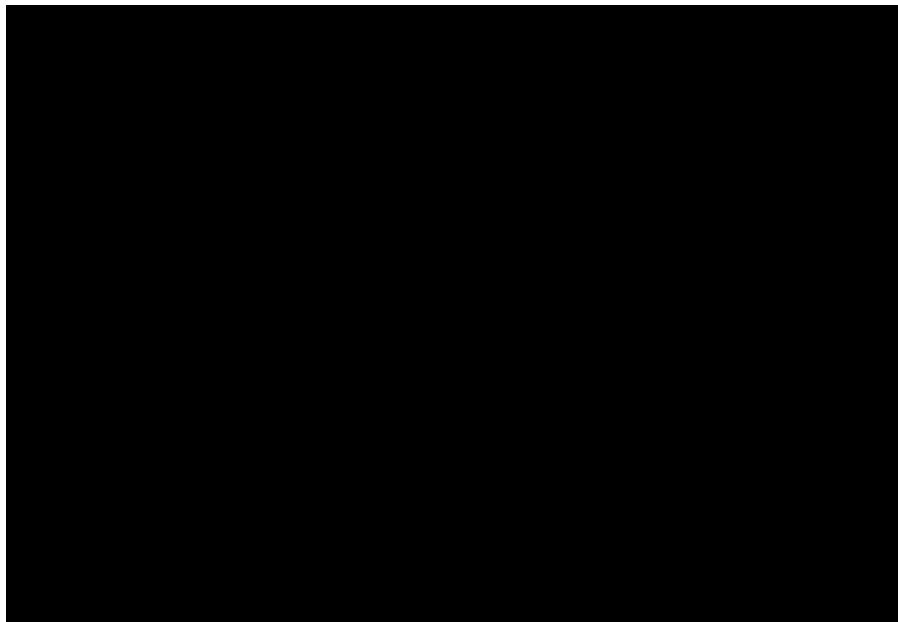
8 54. In fact, Defendants have no data to support any claim that Penuma will cause an
9 increase in penile length. To the contrary, implantation of the Penuma device frequently causes
10 scarring, resulting in the penis becoming shorter. When the Penuma is placed, a sheath of scar
11 tissue—termed a “pseudocapsule”—forms around the entire foreign body. This is the body’s
12 reaction to healing. Because scar tissue does not stretch, when the penis fills with blood during an
13 erection, the ventral surface of the penis stretches and becomes longer, but the dorsal surface is
14 restricted by the pseudocapsule. This results in a dorsal curvature and apparent shortening of
15 the erection. Neither IMD nor Dr. Elist acknowledges these complications. Instead, their website
16 simply shuffles consumers to their self-published study—a study which Dr. Elist himself admits
17 had skewed results because over a hundred patients (approximately 24% of the potential pool)
18 refused to participate.

19 55. Dr. Elist and IMD similarly tout that the post-Penuma penis is “natural looking,”
20 indicating that it is effective for cosmetic enhancement in men with normal, healthy penises;
21
22
23
24
25
26
27
28

1 however, many patients experience a penguin or batwing shape post-surgery, causing the body of
2 the penis to be wider than the head of the penis:



10 56. Defendants also claim that the Penuma procedure is “reversible.” The prevailing
11 medical literature disagrees, concluding that in “all patients in our series, corrective surgery
12 resulted in both cosmetic and functional improvement. However, **none** resulted in a completely
13 normal penis, as was the appearance prior to initial enhancement surgery”:⁵



27 ⁵ Furr, *Complications of Genital Enlargement Surgery*, 15 SEX. MED. REV. 1811–17, 1816 (2018)
28 (emphasis added).

1 57. Defendants also claim that the Penuma implant causes no interference with normal
2 penis function. Yet many patients experience sexual dysfunction, including loss of sensation, as a
3 consequence of the receiving the Penuma implant.

4 58. Defendants knew when they made these representations that Penuma was not safe and
5 effective or FDA-cleared for cosmetic enhancement of normal penises and that the procedure
6 frequently caused side effects requiring removal of the device. Defendants also knew that the
7 Penuma procedure could not be reversed without permanent damage to the penis, but they
8 nevertheless failed to disclose and actively concealed this information from Plaintiff and the Class
9 members.

10 59. Dr. Elist and other doctors performing Penuma implant surgery regularly refer patients
11 to the Penuma website and to Dr. Elist's website for information regarding the Penuma device. In
12 making the representations and omissions described above, Defendants intend for consumers to
13 rely on their representations that Penuma is a safe and effective, FDA-cleared device for cosmetic
14 penile enlargement that is permanent and reversible, and thousands of reasonable consumers did
15 in fact so rely.

16 60. Plaintiff and the Class members purchased the Penuma device and implantation
17 procedure in reasonable reliance on Defendants' misrepresentations that Penuma was safe and
18 effective and FDA-cleared for cosmetic enhancement and that it was permanent and could be
19 reversed without negative consequences. Plaintiff and Class members also relied on Defendants'
20 misrepresentations that the Penuma implant would result in a natural looking penis and that the
21 implant would cause no interference with normal penis function. If Plaintiff and the Class members
22 had known that Penuma was not safe and effective or FDA-cleared for the cosmetic enhancement
23 of normal penises, that Defendants in fact had no data to support any claims of increase in penis
24 length as a result of the procedure, that the implant often interfered with normal penis function,
25 and that the procedure frequently led to complications requiring removal of the device, resulting
26 in permanent damage to the penis, they would not have purchased the device and would not have
27 had the implantation procedure performed.

1 **C. Plaintiff and the Class members paid thousands of dollars for a product and service**
2 **that had no value.**

3 61. The total cost for purchase of the Penuma device and the implantation surgery ranges
4 from \$15,000–\$20,000. Of this payment, approximately \$6,000 is paid to IMD for purchase of the
5 Penuma device. Because the procedure is cosmetic, it is not covered by medical insurance. All
6 Defendants profit, either directly or indirectly, from the sales of the Penuma device to patients.

7 62. Dr. Elist has performed thousands of Penuma implantation procedures at his clinic in
8 Beverly Hills. He has also, with Gesiva’s help, marketed and licensed his Penuma implantation
9 procedures to 12 doctors nationwide, who all perform the surgery in substantially the same manner,
10 using the product and procedure developed by Dr. Elist in his Beverly Hills clinic, resulting in
11 substantial profits to Defendants.

12 63. The actual value of the procedure, however, is non-existent. Instead of the cosmetic
13 enlargement of the penis consumers were misled to expect, Penuma does not increase the length
14 of patients’ flaccid penises, but causes disfigurement and scarring that often leads to a shortening
15 of the erect penis in the majority of cases. The scarring also often interferes with normal penis
16 function by reducing sensation in the penis, leading to sexual dysfunction.

17 64. Not only does the procedure not produce the cosmetic enhancement consumers are
18 misled to expect, but it also frequently causes painful infections that lead to yet more scarring. A
19 substantial number of men have had to have the Penuma device removed because of such infection
20 and scarring, leading to a loss of sensation in and/or permanent shortening of the penis.

21 65. When infection, disfigurement, or other complications require the Penuma to be
22 removed, patients suffer a significant shortening of their non-erect penises. Because the
23 pseudocapsule of scar tissue, which is attached to the penile shaft, contracts over time after
24 removal of the Penuma device, patients’ flaccid penises appear shorter—often one to two inches
25 shorter. The same shortening appears in the erect penises of patients who have had the Penuma
26 removed.

1 66. These complications have been well-reported in medical literature. A 2021 article
2 specially identified “penile shortening and erectile dysfunction (ED)” as “reported complications
3 in literature” following Penuma removal.⁶ A 2018 article also from the Journal of Sexual Medicine
4 similarly identified “penile shortening due to fibrosis.”⁷

5 67. Given these risks, reputable urologists recognize that penile implant procedures,
6 including the Penuma procedure, are not safe and effective for cosmetic enhancement in men with
7 normal penises. For example, the Mayo Clinic notes that penis-enlargement surgery is
8 “experimental” and should be reserved for “men whose penises don’t function normally because
9 of a birth defect or injury”:

10 The need for penis-enlargement surgery is rare. Surgery is typically
11 reserved for men whose penises don't function normally because of
12 a birth defect or injury. Although some surgeons offer cosmetic
13 penis enlargement using various techniques, it's controversial and
considered by many to be unnecessary and in some cases
permanently harmful. These surgeries should be considered
experimental.

14 Mayo Clinic, *Penis-enlargement products: Do they work?*, available at [https://www.mayoclinic](https://www.mayoclinic.org/healthy-lifestyle/sexual-health/in-depth/penis/art-20045363)
15 [.org/healthy-lifestyle/sexual-health/in-depth/penis/art-20045363](https://www.mayoclinic.org/healthy-lifestyle/sexual-health/in-depth/penis/art-20045363) (last visited Sept. 23, 2021); *see*
16 *also Marra, Systematic Review of Surgical and Nonsurgical Interventions in Normal Men*
17 *Complaining of Penis Size*, 8 SEX. MED. REV. 158, 177 (2020) (“We believe that surgery should
18 be a last resort, undertaken as an experimental treatment only in a clinical trial setting after expert
19 psychosexual assessment.”)

20 68. As a result of their reliance on Defendants’ representations and omissions, consumers
21 have suffered an ascertainable loss of money, namely, the cost of purchasing the Penuma device
22 and procedure. Further, as a result of their deceptive marketing and unfair competition, Defendants
23 realized sizable profits.

24
25
26 _____
27 ⁶ Kapadia et al., *Evaluation and Treatment of Complications of Penuma Penile Implant*, 18
JOURNAL OF SEXUAL MEDICINE 80 (2021).

28 ⁷ Furr et al., *Complications of Genital Enlargement Surgery*, 15 J. SEX. MED. 1811 (2018).

1 69. As the intended, direct, and proximate result of Defendants' false, misleading, and
2 deceptive representations and omissions, Defendants have been unjustly enriched through sales of
3 Penuma devices and procedures at the expense of Plaintiff and the Class members.

4 70. If the Penuma device and procedure were redesigned to be safe and effective for
5 cosmetic penile enlargement, FDA-cleared for this use, and truthfully marketed, there is a
6 possibility that Plaintiff would purchase a Penuma device and procedure in the future.

7 71. Plaintiff and the Class members suffered injuries in fact caused by the false,
8 fraudulent, unfair, deceptive, and misleading practice alleged herein and accordingly seek
9 restitution and injunctive relief.

10 **D. Class Definition**

11 Plaintiff brings this lawsuit as a class action on behalf of himself and on behalf of the
12 following Class and Sub-Class:

13 **Class:**

14 All individuals in the United States, including its territories and the
15 District of Columbia, who purchased a Penuma device and
16 implantation procedure from four years prior to the filing of this
17 complaint through the date of certification.

18 **Sub-Class:**

19 All Class members whose procedures were performed by Dr. James
20 Elist at the Beverly Hills South Pacific Surgery Center.

21 Excluded from the Class and Sub-Class are (1) any employees, officers, directors, or immediate
22 family members of Defendants; (2) any attorneys appearing in this case; (3) any judges assigned
23 to hear this case, as well as their immediate family and staff; (4) any judges who may hear an
24 appeal in this case, as well as their immediate family and staff; (5) any individuals whose Penuma
25 implantation procedures were covered by medical insurance; (6) any individuals who have been
26 diagnosed with a soft tissue deformity of the penis; and (7) any individuals who have filed an
27 individual action for personal injuries caused by the Penuma device and/or procedure.

28 72. **Ascertainability. FED. R. CIV. P. 23(a).** The Class and Subclass are ascertainable in
that they comprise individuals who can be identified by reference to purely objective criteria,

1 including information in Defendants' business records. Notice may be mailed to members of the
2 Class and Subclass using the information in Defendants' files, as updated through the National
3 Change of Address Registry and other commercially available means.

4 **73. Numerosity. FED. R. CIV. P. 23(a)(1).** The Class and Subclass are so numerous that
5 joinder of all members is impracticable. Although the precise number of Class and Subclass
6 members is not currently known, the scope of Penuma's sales and Dr. Elist's practice shows that
7 the Class and Subclass likely consist of at least hundreds of persons and, therefore, it would be
8 impracticable to bring all these persons before the Court as individual plaintiffs.

9 **74. Typicality. FED. R. CIV. P. 23(a)(3).** Plaintiff's claims are typical of each member of
10 the Class and Subclass he seeks to represent. These claims all arise from the same operative facts
11 and are based on the same legal theories.

12 **75. Adequacy of Representation. FED. R. CIV. P. 23(a)(4).** Plaintiff will fairly and
13 adequately protect the interests of the Class and Subclass members. Plaintiff is committed to
14 vigorously litigating this matter, and his interests are aligned with those of the Class and Subclass.
15 Plaintiff has retained counsel experienced in handling consumer class action litigation.

16 **76. Commonality and Predominance. FED. R. CIV. P. 23(a)(2) & (b)(3).** Common
17 issues of law and fact exist regarding Plaintiff's and the Class and Subclass members' claims and
18 predominate over any individual issues. These common issues include:

- 19 (a) whether Defendants misrepresented that Penuma was FDA-cleared for
20 cosmetic enhancement of normal penises;
- 21 (b) whether the Penuma device and procedure are safe and effective for
22 cosmetic penis enlargement;
- 23 (c) whether Defendants falsely and misleadingly marketed Penuma as a
24 cosmetic penis enlargement device;
- 25 (d) whether Defendants misrepresented that Penuma was permanent;
- 26 (e) whether Defendants misrepresented that the Penuma procedure was
27 reversible;
- 28 (f) whether Defendants misrepresented that the Penuma device results in a
normal looking penis;

- 1 (g) whether Defendants misrepresented that the Penuma device causes no
2 interference with penile function;
- 3 (h) whether Defendants’ marketing of the Penuma device and procedure is an
4 unfair business practice;
- 5 (i) whether Defendants violated California’s False Advertising Law;
- 6 (j) whether Defendants violated California’s Consumer Legal Remedies Act;
- 7 (k) whether Defendants violated California’s Unfair Competition Law;
- 8 (l) whether injunctive relief is appropriate; and
- 9 (m) the appropriate measure of restitution.

10 77. **Superiority. FED. R. CIV. P. 23(b)(3).** A class action is a superior method for the fair
11 and efficient adjudication of this controversy. The interests of Class and Subclass members in
12 individually controlling the prosecution of separate claims against Defendant is small, as the
13 maximum damages recoverable by any one Class member is limited. Management of the Class’s
14 claims in a single proceeding will avoid inconsistent judgments and result in a more efficient use
15 of judicial resources than resolving these same issues in many individual cases.

16 78. **Injunctive Relief Appropriate to the Class. FED. R. CIV. P. 23(b)(2).** This action
17 should also be maintained as a class action because Defendants have acted or refused to act on
18 grounds that apply generally to the Class and Subclass, so that final injunctive relief or
19 corresponding declaratory relief is appropriate respecting the Class and Subclass as a whole.

20 VII. CLAIMS

21 COUNT ONE – Violation of California’s False Advertising 22 Law, CAL. BUS. & PROF. CODE § 17500 (“FAL”)

23 79. Plaintiff incorporates by reference all of the foregoing allegations as if they were fully
24 set forth here.

25 80. Plaintiff brings this claim individually and on behalf of the Class and Subclass
26 members against all Defendants.

27 81. The FAL provides that “[i]t is unlawful for any person, firm, corporation or
28 association, or any employee thereof with intent directly or indirectly to dispose of real or personal

1 property or to perform services” to disseminate any statement “which is untrue or misleading, and
2 which is known, or which by the exercise of reasonable care should be known, to be untrue or
3 misleading.” CAL. BUS. & PROF. CODE § 17500.

4 82. It is also unlawful under the FAL to disseminate statements concerning property or
5 services that are “untrue or misleading, and which [are] known, or which by the exercise of
6 reasonable care should be known, to be untrue or misleading.” *Id.*

7 83. As alleged herein, Defendants’ advertisements relating to the Penuma device and
8 implantation procedure misled reasonable consumers as to the uses for which Penuma had been
9 cleared for use by the FDA, as to its safety and effectiveness for use as a penis enlargement device,
10 and as to whether the procedure was permanent, natural looking, and reversible.

11 84. Defendants’ business practices alleged herein constitute deceptive, untrue, and
12 misleading advertising pursuant to the FAL because Defendants knew or reasonably should have
13 known that their advertisements were untrue and misleading, and Defendants omitted material
14 information from their advertising.

15 85. Defendants profited from their sale of the falsely and deceptively advertised device
16 and procedure.

17 86. As a result, Plaintiff, the Class and Subclass, and the general public are entitled to
18 injunctive and equitable relief, restitution, and an order for the disgorgement of the funds by which
19 Defendants were unjustly enriched.

20 87. Pursuant to CAL. BUS. & PROF. CODE § 17535, Plaintiff, on behalf of himself and the
21 Class and Subclass, seeks an order enjoining Defendants from continuing to engage in deceptive
22 business practices and false advertising.

23 **COUNT TWO – Violation of California’s Consumers Legal**
24 **Remedies Act, CAL. CIV. CODE § 1750 *et seq.* (“CLRA”)**

25 88. Plaintiff incorporates by reference all of the foregoing allegations as if they were fully
26 set forth here.

1 89. Plaintiff brings this claim individually and on behalf of the Class and Subclass
2 members against all Defendants.

3 90. The California Consumer Legal Remedies Act (“CLRA”) prohibits deceptive
4 practices in connection with the conduct of a business that provides goods, property, or services
5 primarily for personal, family, or household purposes.

6 91. Defendants are “person(s)” as defined by CAL. CIV. CODE § 1761(c).

7 92. Plaintiff and the Class and Subclass members are “consumers” within the meaning of
8 CAL. CIV. CODE § 1761(d) because they purchased the Penuma device and procedure for personal
9 purposes.

10 93. Defendants’ false and misleading advertising was designed to and did induce the
11 purchase of the Penuma device and implantation procedure for personal, family, or household
12 purposes by Plaintiff and the Class and Subclass members, in violation of the following sections
13 of the CLRA:

- 14 (a) § 1770(a)(5): representing that goods have characteristics, uses, or
15 benefits which they do not have;
- 16 (b) § 1770(a)(7): representing that goods are of a particular standard,
17 quality, or grade if they are of another; and
- 18 (c) § 1770(a)(9): advertising goods with intent not to sell them as
19 advertised.

20 94. Defendants knew the Penuma device and procedure did not possess the characteristics
21 and benefits as represented and were not of the particular standard, quality, or grade as represented.

22 95. Defendants had a duty to Plaintiff and the Class and Subclass members to disclose the
23 scope of intended uses for which the Penuma device and procedure were safe and effective and
24 FDA-cleared because:

- 25 (a) Defendants were in a superior position to know the scope of intended
26 uses for which the Penuma device and procedure were safe and
27 effective and FDA-cleared;
- 28 (b) Plaintiff and the Class and Subclass members could not reasonably
have been expected to know the scope of intended uses for which the
Penuma device and procedure were safe and effective and FDA-
cleared; and

1 (c) Defendants knew that Plaintiff and the Class and Subclass members
2 could not reasonably have been expected to know the scope of intended
3 uses for which the Penuma device and procedure were safe and
4 effective and FDA-cleared.

5 96. In failing to disclose and misrepresenting the scope of intended uses for which the
6 Penuma device and procedure were safe and effective and FDA-cleared, Defendants knowingly
7 and intentionally concealed material facts and breached their duty not to do so.

8 97. The facts Defendants concealed from and/or misrepresented to Plaintiff and the Class
9 members are material in that a reasonable consumer would have considered them to be important
10 in deciding whether to purchase the Penuma device and procedure. If Plaintiff and the Class
11 members had known that Penuma was not safe and effective or FDA-cleared for cosmetic
12 enhancement of normal penises, or that it was not permanent and frequently led to complications
13 requiring removal, causing permanent damage to the penis, they would not have purchased the
14 device and procedure.

15 98. Plaintiff and the Class and Subclass members are reasonable consumers who expect
16 device manufacturers and medical service providers like Defendants to provide accurate and
17 truthful representations regarding the safety and efficacy of their products. Further, reasonable
18 consumers, like Plaintiff and the Class and Subclass members, rely on the representations made
19 by device manufacturers and medical service providers regarding the safety and efficacy of their
20 medical devices in determining whether to purchase and consider that information important to
21 their purchase decision.

22 99. Defendants profited from the sale of the falsely, deceptively, and unlawfully
23 advertised device and procedure to consumers.

24 100. Defendants' wrongful business practices constituted, and constitute, a continuing
25 course of conduct in violation of the CLRA.

26 101. Pursuant to the provisions of CAL. CIV. CODE § 1782(a), Plaintiff will provide a letter
27 to Defendant concurrently with the filing of this Original Class Action Complaint with notice of
28 its alleged violations of the CLRA, demanding that Defendants correct such violations, and

1 providing them with the opportunity to correct their business practices. If Defendants do not
2 thereafter correct their business practices, Plaintiff will amend the complaint to add claims for
3 monetary relief, including restitution under the CLRA.

4 102. Pursuant to CAL. CIV. CODE § 1780, Plaintiff seeks injunctive relief, his reasonable
5 attorney fees and costs, and any other relief that the Court deems proper.

6
7 **COUNT THREE – Violation of California’s Unfair
Competition Law, CAL. BUS. & PROF. CODE § 17200 *et seq.*
8 (“UCL”)**

9 103. Plaintiff incorporates by reference all of the foregoing allegations as if they were fully
10 set forth here.

11 104. Plaintiff brings this claim individually and on behalf of the Class and Subclass against
12 all Defendants.

13 105. The UCL prohibits acts of unfair competition, including any “unlawful, unfair or
14 fraudulent business act or practice” and “unfair, deceptive, untrue or misleading advertising.” CAL.
15 BUS. & PROF. CODE § 17200.

16 106. Defendants’ business acts and practices alleged herein are unlawful in that they
17 violate:

- 18 (d) The False Advertising Law, CAL. BUS. & PROF. CODE §§ 17500 *et seq.*
19 (e) The Consumer Legal Remedies Act, CAL. CIV. CODE §§ 1750 *et seq.*;
20 (f) The Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 *et seq.*; and
21 (g) The California Sherman Food, Drug, and Cosmetic Law, CAL. HEALTH &
SAFETY CODE §§ 110100 *et seq.*

22 107. Defendants’ conduct alleged herein was also unfair because this conduct is immoral,
23 unethical, unscrupulous, and substantially injurious to consumers. The utility of Defendants’
24 conduct is non-existent and does not outweigh the gravity of the harm to Plaintiff and the Class
25 members.

26 108. Defendants’ conduct is also unfair because it violates public policy as declared by
27 specific statutory and regulatory provisions, including but not limited to the applicable sections of
28

1 the False Advertising Law, the Consumer Legal Remedies Act, the federal Food, Drug, and
2 Cosmetic Act, and the California Sherman Food, Drug, and Cosmetic Law.

3 109. Defendants' conduct alleged herein was also fraudulent because an objective,
4 reasonable consumer is likely to be misled by Defendants' claims to believe that Penuma is safe
5 and effective and FDA-cleared for cosmetic enhancement of normal penises, as well as that the
6 procedure is permanent and reversible.

7 110. Defendants profited from their sale of the falsely, deceptively, and unlawfully
8 advertised device and procedure to consumers.

9 111. Plaintiff and the Class and Subclass members are likely to continue to be damaged by
10 Defendants' deceptive trade practices, because if the Penuma device and procedure were
11 redesigned to be safe and effective for cosmetic penile enlargement, FDA-cleared for this use, and
12 truthfully marketed, there is a possibility that Plaintiff and the Class and Subclass members would
13 purchase a Penuma device and procedure in the future. Thus, injunctive relief enjoining
14 Defendants' false and misleading advertising is proper.

15 112. Defendants' conduct has caused and continues to cause substantial injuries in fact to
16 Plaintiff and Class and Subclass members. As a result of their reliance on Defendants'
17 misrepresentations and omissions, Plaintiff and the Class and Subclass members suffered
18 ascertainable losses of money and property—namely the money they paid for the valueless
19 Penuma device and implantation procedure.

20 113. In accordance with CAL. BUS. & PROF. CODE § 17203, Plaintiff seeks an order
21 enjoining Defendant from continuing to conduct business through unlawful, unfair, and/or
22 fraudulent acts and practices.

23 114. Plaintiff, on behalf of the California Class and Subclass, also seeks an order for
24 restitution of all monies from the sale of the Penuma device and implantation procedure, which
25 were unjustly acquired through acts of unlawful competition.

1 **VIII. CONCLUSION AND PRAYER**

2 WHEREFORE, Plaintiff, individually and on behalf of the Class and Subclass, respectfully
3 requests that the Court enter judgment ordering relief as follows:

- 4 (a) certifying the Class and Subclass pursuant to FED. R. CIV. P. 23(b)(3)
5 and/or (b)(2);
- 6 (b) appointing Plaintiff to represent the Class and Subclass;
- 7 (c) appointing Plaintiff’s counsel as Class Counsel;
- 8 (d) enjoining Defendants from further deceptive advertising, marketing,
9 and other false and misleading business practices with respect to their
10 representations regarding the Penuma device and procedure;
- 11 (e) enjoining Defendants to cease and desist stating that Penuma is “FDA-
12 cleared for cosmetic enhancement” on their websites and in
13 advertisements and other marketing materials without disclosing that it
14 is cleared for use only for “use in the cosmetic correction of soft tissue
15 deformities.”
- 16 (f) awarding Plaintiff and the Class and Subclass members restitution in
17 an amount to be proven at trial;
- 18 (g) awarding Plaintiff and the Class and Subclass members reasonable
19 attorneys’ fees, expenses, and costs of suit pursuant to CAL. CODE CIV.
20 P. § 1021.5;
- 21 (h) awarding pre-judgment and post-judgment interest, as provided by law;
- 22 (i) granting leave to amend the Complaint to conform to the evidence
23 produced at trial; and
- 24 (j) awarding such other relieve as this Court may deem just and proper.

25 **IX. DEMAND FOR JURY TRIAL**

26 Plaintiff hereby demands a trial by jury on all issues so triable.
27
28

1 Dated: December 10, 2021

Respectfully submitted,

2 By: /s/ Michael A. Caddell

3 Michael A. Caddell (SBN 249469)

4 mac@caddellchapman.com

Cynthia B. Chapman (SBN 164471)

5 cbc@caddellchapman.com

Amy E. Tabor (SBN 297660)

6 aet@caddellchapman.com

CADDELL & CHAPMAN

7 P.O. Box 1311

Monterey CA 93942

8 Tel.: (713) 751-0400

9 Fax: (713) 751-0906

Attorneys for Plaintiff

10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

ClassAction.org

This complaint is part of ClassAction.org's searchable class action lawsuit database and can be found in this post: [Penuma Penile Implant Neither Safe Nor Effective for Advertised Purpose, Class Action Alleges](#)
