September 30, 2022

Augmenta LLC
% Lisa L. Pritchard, BSEEE
Vice President, Regulatory, Quality, Clinical & Engineering
DuVal & Associates, P.A.
1820 Medical Arts Building
825 Nicollet Mall
Minneapolis, MN 55402

Re: K200073
Trade/Device Name: Augmenta Penile Implant
Regulation Number: 21 CFR§ 874.3620
Regulation Name: Ear, Nose, and Throat Synthetic Polymer Material
Regulatory Class: II
Product Code: MIB
Dated: August 4, 2022
Received: August 4, 2022

Dear Lisa L. Pritchard:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for
Mark J. Antonino, M.S.
Assistant Director
DHT3B: Division of Reproductive,
Gynecology and Urology Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K200073

Device Name
Augmenta Penile Implant

Indications for Use *(Describe)*
The Augmenta Penile Implant is an implantable device intended for use in the cosmetic correction of soft tissue deformities, and is trimmed to length at the surgeon's discretion for a custom implant.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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AUGMENTA

510(k) Summary

510(k) Owner:

Augmenta LLC
1315 St. Joseph Parkway
Suite 1700
Houston, TX 77002
Telephone: 713.205.4674
Contact: Robert J. Cornell, MD
Date prepared: September 28, 2022

Device Name:

Trade Name: Augmenta Penile Implant
Common Name: Elastomer, Silicone Block
Classification Name: Ear, Nose, and Throat Synthetic Polymer Material
Regulation: 21 CFR §874.3620
Regulatory Classification: 2
Product Code: MIB

Predicate Device:

Pre-Formed Penile Silicone Block (K181387)
The predicate device has not been subject of a design-related recall.

Device Description:

The Augmenta Penile Implant is an implantable device intended for use in the cosmetic correction of soft tissue deformities, and is trimmed to length at the surgeon's discretion for a custom implant. The Augmenta Penile Implant is made of silicone. The Augmenta Penile Implant comes in 175 sizes with a range of dimensions. The proximal end of the device may be trimmed by the physician to further customize the fit. The device is provided sterile and is intended for single-use only.

Table 1: Augmenta Penile Implant Size Ranges

Measurement	Augmenta Size Range
Natural Girth Circumference (Inner Circumference)	5.5 – 13.0 cm
Augmented Girth Circumference (Outer Circumference)	8.5 – 16.0 cm
Ventral Gap	1.5 – 3.0 cm
Total Length (L)	8.0 - 18.0 cm

Indications for Use

The Augmenta Penile Implant is an implantable device intended for use in the cosmetic correction of soft tissue deformities, and is trimmed to length at the surgeon's discretion for a custom implant.

Comparison of Technological Characteristics with the Predicate Device
The Augmenta Penile Implant has similar technological characteristics as the predicate device, the Pre-formed Penile Silicone Block cleared via K181387. A comparison of the devices is provided in Table 2.

Table 2: Comparison with Predicate Device

Device Comparison	Subject Device Augmenta Penile Implant	Predicate Device Pre-formed Penile Silicone Block (Penuma) (K181387)
Name	Augmenta Penile Implant	Pre-Formed Penile Silicone Block (Penuma)
Manufacturer	Augmenta, LCC	International Medical Devices, Inc
FDA Product Code	MIB	MIB
Indications for Use	The Augmenta Penile Implant is intended for use in the cosmetic correction of soft tissue deformities, and is trimmed to length at the surgeon's discretion for a custom implant.	The Pre-Formed Penile Silicone Block is intended for use in the cosmetic correction of soft tissue deformities, and is contoured at the surgeon's discretion to create a custom implant.
Principles of Operation	The Augmenta Penile Implant may be used in a variety of surgical techniques. Therefore, the surgeon is best advised to use the method that his/her own practice and discretion dictate to be best for the patient.	The Penuma device may be used in a variety of surgical techniques. Therefore, the surgeon is best advised to use the method that his/her own practice and discretion dictate to be best for the patient.
Device Material	Silicone	Medical grade silicone with an embedded polyester mesh.
Device Coating	Hydrophilic coating	No coating
Device Offerings	175 device offerings Augmented Girth: 8.5 – 16.0 cm Natural Girth: 5.5 – 13.0 cm Ventral Gap: 1.5 – 3.0 cm Length: 8.0 – 18.0 cm	3 device offerings (L, XL, XXL)
Device Length	8.0 - 18.0 cm length	12 – 18 cm length
Device Size	Calculated:[1] Height: 2.3 – 3.4 cm Thickness: 0.54 – 0.8 cm	Height: 2.0 – 3.5 cm Thickness: 0.5 – 1.1 cm
Condition of Use	Single Use	Single Use
Sterilization Method	Ethylene Oxide	Ethylene Oxide

[1]Height and thickness are calculated measurements for Augmenta; specifications are for natural girth (inner circumference), augmented girth (outer circumference), and ventral gap.

Non-Clinical Performance Data
No FDA performance standards have been promulgated that are applicable to the Augmenta Penile Implant.

The Augmenta Penile Implant is considered an implantable medical device with permanent (greater than 30 day) tissue/bone contact. The following assessments demonstrated safety in accordance with ISO 10993-1:

- Cytotoxicity
- Sensitization
- Irritation/intracutaneous reactivity
- Acute Systemic Toxicity
- Material-Mediated Pyrogenicity
- Implantation
- Genotoxicity
- Extractables and Leachables
- Toxicology Risk Assessment

Additional non-clinical performance testing included evaluations of product and packaging integrity and acceptability of the sterilization processing These included visual integrity, seal strength, shipping, burst test, sterilization validation, EO residual, and image artifact evaluations. These assessments were conducted in accordance with the following recognized standards:

- ASTM D4169-16
- ASTM F88/F88M-15
- ASTM F1140/F1140M-13
- ISO 111135: 2014
- ISO 10993-7: 2008
- F2119-07 (2013)

Conclusion

The biocompatibility testing, extractable/leachable chemical analysis, toxicological risk assessment, product and packaging integrity, sterilization assessments, and image artifact testing conducted provides evidence that the Augmenta Penile Implant performs comparable to the legally marketed predicate device. The Augmenta Penile Implant has the same intended use as the predicate device. The data provided supports substantial equivalence of the Augmenta Penile Implant to the predicate device.