January 23, 2019

International Medical Devices, Inc.
% Allison Komiyama, Ph.D., RAC
Principal Consultant
AcKnowledge Regulatory Strategies, LLC
2834 Hawthorn St.
San Diego, CA 92104

Re: K181387
Trade/Device Name: Pre-Formed Penile Silicone Block
Regulation Number: 21 CFR 874.3620
Regulation Name: Ear, Nose, and Throat Synthetic Polymer Material
Regulatory Class: Class II
Product Code: MIB
Dated: December 19, 2018
Received: December 26, 2018

Dear Allison Komiyama:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Glenn B. Bell -S

for
Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K181387

Device Name
Pre-Formed Penile Silicone Block

Indications for Use *(Describe)*
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.

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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510(k) Summary
K181387

DATE PREPARED
December 19, 2018

MANUFACTURER AND 510(k) OWNER
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PROPRIETARY NAME OF SUBJECT DEVICE
Pre-Formed Penile Silicone Block

COMMON NAME
Elastomer, Silicone Block

DEVICE CLASSIFICATION
21 CFR 874.3620, Product Code MIB, Class II

CLASSIFICATION NAME
Ear, nose, and throat synthetic polymer material

PREDICATE DEVICE IDENTIFICATION
The Pre-Formed Penile Silicone Block is substantially equivalent to the following predicates:

510(k) Number	*Predicate Device Name / Manufacturer*	*Primary Predicate*
K162624	Pre-Formed Penile Silicone Block / International Medical Devices, Inc.	✓

DEVICE DESCRIPTION
The Pre-Formed Penile Silicone Block is made from medical grade silicone with an embedded polyester mesh. The device comes in variations that include three sizes (L, XL, and XXL) and one durometer ("Soft"). Size "L" is 12 cm in length with a maximum thickness of 0.5 cm and a height of 2 cm. Size "XL" is 15 cm in length with a maximum thickness of 0.8 cm and a height of 3 cm. Size "XXL" is 18 cm in length with a maximum

thickness of 1.1 cm and a height of 3.5 cm. The device is used in the cosmetic correction of soft tissue deformities in the penis, and may be trimmed to allow the surgeon to tailor the device to the needs of a specific patient.

INDICATIONS FOR USE

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.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

IMD believes that the Pre-Formed Penile Silicone Block is substantially equivalent to the predicate device based on the information summarized here:

The subject device has identical dimensions, the same indications for use, and the same design as the device cleared in K162624. The subject device has similar materials and similar technological characteristics to the device cleared in K162624. Testing submitted in this premarket notification demonstrates that including a new medical grade silicone material does not affect the safety and effectiveness of this device.

SUMMARY OF NON-CLINICAL TESTING

No FDA performance standards have been established for the Pre-Formed Penile Silicone Block. A summary of the following tests that were performed was provided in order to demonstrate safety based on current industry standards:

- Biocompatibility Risk Assessment per ISO 10993-1
- Cytotoxicity testing per ISO 10993-5
- Extractable/Leachable Chemical Analysis (GC/MS, ICP/MS, ICP/AES, LC/MS)
- Toxicological Risk Assessment per ISO 10993-17

The results of these tests indicate that the Pre-Formed Penile Silicone Block is substantially equivalent to the predicate device.

CONCLUSION

Based on the biocompatibility testing, extractable/leachable chemical analysis, and toxicological risk assessment performed, it can be concluded that the subject device does not raise new issues of safety and effectiveness compared to the predicate device. The identical indications for use and similar technological characteristics for the proposed Pre-Formed Penile Silicone Block are assessed to be substantially equivalent to the predicate device.