DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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February 1, 2017

International Medical Devices, Inc.
% Allison Komiyama
Principal Consultant
Acknowledge Regulatory Strategies
2834 Hawthorn St.
San Diego, CA 92104

Re: K162624
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 20, 2016
Received: December 22, 2016

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Benjamin R. Fisher -S

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K162624

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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

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510(k) Summary
K162624

DATE PREPARED
January 27, 2016

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

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.

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.

510(k) Summary

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*
K042380	Silicone Block / National Medical Devices, Inc.*	✓
K040042	Medisil Silicone Sheeting / Medisil Corporation	
K022511	AART Calf Implant / Aesthetic and Reconstructive Technologies, Inc.	
K021839	AART Gluteal Implant / Aesthetic and Reconstructive Technologies, Inc.	

* National Medical Devices, Inc. is now International Medical Devices, Inc.

SUMMARY OF NON-CLINICAL TESTING

No FDA performance standards have been established for the Pre-Formed Penile Silicone Block. No additional non-clinical testing was provided in this submission in order to demonstrate substantial equivalence.

SUMMARY OF CLINICAL TESTING

Clinical evidence on 100 patients was collected to evaluate the risks of migration, erosion, and pain. After the surgical procedure, follow-up data for all patients was collected and evaluated at the following time points: the three successive days following the procedure, and at two weeks, one month, three months, six months, and twelve months following the procedure.

Pain was assessed post-operatively using a validated 0 to 10 Comparative Pain Scale. In 100 patients the weighted average pain rating across the patient population reviewed was 3.2. Pain relief was experienced on average in 7.2 days. In 100 patients there were 3 cases of erosion. This adverse event was observed by the clinic on average 8 months after the patient's procedure with a minimum of 6 months and a maximum of 10 months. In 100 patients there were 4 cases of migration. This adverse event was observed by the clinic on average 1.5 months after the patient's procedure with a minimum of 1 month and a maximum of 2 months. In 100 patients there were 3 cases of infection. This adverse event was observed by the clinic on average 3.5 months after the patient's procedure with a minimum of 2.5 months and a maximum of 4.5 months. 3 out of the 3 cases of erosion and 3 out of the 4 cases of migration were determined to be caused by failure of the patient to follow post-operative instructions (e.g., avoid use of external devices for the stretching/expansion of penile skin). Labeling to mitigate these risks has been added to the package insert in order to more directly address post-operative care.

IMD believes that the unique anatomy, physiology, and function of the penis does not increase the overall potential risks compared to the predicate devices. Clinical evidence demonstrates that rates of pain, erosion, migration, and infection are low compared to reports of other silicone implants on the market.

EQUIVALENCE TO PREDICATE DEVICES

International Medical Devices, Inc. believes that the Pre-Formed Penile Silicone Block is substantially equivalent to the predicate devices based on the information summarized here:

The subject device has a similar design and dimensions, has an equivalent intended use, and uses identical materials as the device cleared in K042380. The subject device has similar or identical technological characteristics to the devices cleared in K042380, K040042, K022511 and K021839.

CONCLUSION

The Pre-Formed Penile Silicone Block is considered substantially equivalent to the predicate devices based on the similar indications for use, clinical testing, and similar or identical technological characteristics. Based on this comparison, it can be concluded that the subject device does not raise new issues of safety or effectiveness compared to the predicate devices.