February 3, 2023

International Medical Devices, Inc.
% Lucie Dalet
Senior Regulatory Consultant
Rqm+
2251 San Diego Ave, Suite B-257
San Diego, California 92110

Re: K223051
Trade/Device Name: Pre-Formed 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: February 3, 2023
Received: September 29, 2022

Dear Lucie Dalet:

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 and Part 809 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,

Deborah A. Fellhauer -S

Deborah Fellhauer RN, BSN
Assistant Director
Plastic Surgery Skin and Wound Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices | OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality
CDRH | Food and Drug Administration

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)*
K223051

Device Name
Pre-Formed Silicone Block

Indications for Use *(Describe)*
The Pre-Formed 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 to aid in the reconstruction process.

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.

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510(k) Summary
K223051

DATE PREPARED
February 3, 2023

MANUFACTURER AND 510(k) OWNER
International Medical Devices, Inc.
717 North Maple Drive, Beverly Hills, CA 90210, USA
Telephone: (310) 652-2600
Fax: (310) 657-0500
Official Contact: James Elist, MD

REPRESENTATIVE/CONSULTANT
Lucie Dalet, Ph.D.
Allison C. Komiyama, Ph.D., RAC
RQM+
Telephone: +1 (877) 652-0830
Email: ldalet@rqmplus.com, akomiyama@rqmplus.com

DEVICE INFORMATION

Proprietary Name/Trade Name:	Pre-Formed Silicone Block
Common Name:	Elastomer, Silicone Block
Regulation Number:	21 CFR 874.3620
Class:	Class II
Product Code:	MIB
Premarket Review:	Surgical and Infection Control Devices (OHT4)/ DHT4B
Review Panel:	General and Plastic Surgery

PREDICATE DEVICE IDENTIFICATION
The Pre-Formed 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.*	✓
K220760	Pre-Formed Penile Silicone Block / International Medical Devices, Inc.	
K162624 / K181387	Pre-Formed Penile Silicone Block / International Medical Devices, Inc.	

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

DEVICE DESCRIPTION

The Pre-Formed Silicone Block is an implant intended to be used in the aesthetic (cosmetic) correction of soft tissue deformities. The Pre-Formed Silicone Block comes in multiple shapes and sizes (cup-shaped in small, medium and large; crescent-shaped, and rectangular block) and one durometer to accommodate a variety of surgical techniques and implantation sites. All implants are made from medical grade silicone and can be trimmed with a knife or scissors. The trimmable feature allows the surgeon to custom fabricate, at surgery, an implantable implant for a specific surgical indication. The implants are provided either sterile or non-sterile. Devices that are provided non-sterile must be sterilized prior to use.

INDICATIONS FOR USE

The Pre-Formed 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 to aid in the reconstruction process.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

The Pre-Formed Silicone Block is similar to the predicate devices based on the information summarized here:

The subject device has similar shapes and dimensions as the primary predicate cleared in K042380. The Pre-Formed Silicone Block is made from the same materials and manufacturing processes as the predicate devices cleared in K220760 and K181387. The main difference is the addition of new carvable shapes of implants in order to offer additional possibilities to surgeons to accommodate a larger variety of surgical techniques and implantation needs. Since the dimensions of the new shapes are not greater than the dimensions of the shapes of the predicate devices cleared in K042380, K220760, K162624, and K181387, they are not considered as new technological characteristics that would raise different questions of safety and effectiveness.

	Subject Device	Primary Predicate Device	Other Predicates	
	International Medical Devices, Inc. Pre-Formed Silicone Block	National Medical Devices, Inc. Silicone Block K042380	International Medical Devices, Inc. Pre-Formed Penile Silicone Block K220760	International Medical Devices, Inc. Pre-Formed Penile Silicone Block K162624 / K181387
Indications for Use	The Pre-Formed 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 to aid in the reconstruction process.	The 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 to aid in the reconstruction process.	The Pre-Formed Penile Silicone Block is intended for use in augmentation, reconstructive and cosmetic surgery, and is contoured at the surgeon's discretion to create a custom implant. When used in augmentation procedures, the device provides cosmetic augmentation of the penis and is intended for aesthetic purposes	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.
Product Codes	MIB	MIB	MIB	MIB
Regulation Number	21 CFR 874.3620	21 CFR 874.3620	21 CFR 874.3620	21 CFR 874.3620
Class	Class II	Class II	Class II	Class II
Intended Location of Use	Soft tissue deformities	Penis, calf, gluteal, other soft tissue deformities	Penis	Penis
Materials	Silicone Sheeting Coating	Silicone Sheeting	Silicone Sheeting Coating (optional)	Silicone Sheeting Coating (optional)
Shapes	Cup-shaped Crescent-shaped Block	Curvilinear Oval Block	Curvilinear	Curvilinear
Surface	Smooth	Smooth	Smooth	Smooth
Carvable?	Yes	Yes	Yes	Yes
Provided Sterile?	Provided sterile or non-sterile	Provided sterile or non-sterile	Provided sterile or non-sterile	Provided sterile or non-sterile

SUMMARY OF NON-CLINICAL TESTING

Previous testing (i.e., biocompatibility, sterilization validation, and non-clinical performance testing) was leveraged to support a demonstration of substantial equivalence.

SUMMARY OF CLINICAL TESTING

No additional testing was provided in this submission in order to demonstrate substantial equivalence.

CONCLUSION

Based on the identical indications for use, identical materials, similar technological characteristics, and identical manufacturing processes, it can be concluded that the subject device does not raise different questions of safety or effectiveness compared to the predicate devices. The Pre-Formed Silicone Block is considered substantially equivalent to the predicate devices.