Keosan Trading Co.
% Priscilla Chung
Official Correspondent
LK Consulting Group USA, Inc.
18881 Von Karman Ave STE 160
Irvine, California 92612

July 24, 2024

Re: K241150
Trade/Device Name: MISTI Silicone Implant
Regulation Number: 21 CFR 874.3620
Regulation Name: Ear, Nose, And Throat Synthetic Polymer Material
Regulatory Class: Class II
Product Code: MIB, LZK, FWP, MIC
Dated: April 25, 2024
Received: April 25, 2024

Dear Priscilla Chung:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Manuel Bayona -S

Digitally signed by Manuel Bayona -S
Date: 2024.07.24 15:35:36 -04'00'

For Alicia L. Hemphill
Assistant Director
Breast Implant Team
DHT4B: Division of Infection Control and Plastic and Reconstructive Surgery
OHT4: Office of Surgery and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K241150

Device Name
MISTI Silicone Implant

Indications for Use *(Describe)*

MISTI Silicone Implant is intended for the augmentation or reconstruction of the nasal, malar, chin, gluteal, calf and/or pectoral contour.

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

(K241150)

Date: July 24, 2024

1. Applicant / Submitter:

KEOSAN TRADING CO.
#805, #806, Human Teco B/D, 57, Achasan-ro 17-gil
Seongdong-gu, Seoul, Republic of Korea
Tel: +82-2-466-1188

2. Submission Correspondent:

Priscilla Chung
LK Consulting Group USA, Inc.
18881 Von Karman Ave STE 160
Irvine CA 92620
Phone: 714-202-5789 Fax: 714-409-3357
Email: juhee.c@lkconsultinggroup.com

3. Device:

Proprietary Name:	MISTI Silicone Implant
Common Name:	Silicone Implant
Classification:	21CFR§874.3620 MIB (Elastomer, Silicone Block); 21CFR§878.3550 LZK (Implant, Malar); 21CFR§878.3550 FWP (Prosthesis, Chin, Internal) 21CFR§874.3620 MIC (Implant, Muscle, Pectoralis)

4. Predicate Device:

- Primary Predicate Device: SOFTXIL (K171851) by BISTOOL Inc.
- Reference Devices:
  Gluteal Implant, models RND 5-X, TRD 6-X (K052504) by Implantech Associates, Inc.
  Calf Implant, model EC17-X (K052505) by Implantech Associates, Inc.
  Pectoralis Implant (K952708) by Spirit Ridge Technologies
  Customized Contour Implant (K200610) by Implantech Associates, Inc.

5. Device Description:

The MISTI Silicone Implant offers various types including Nasal, Chin, Mid-face, Forehead, Block, Temple, Gluteal, Calf and Pectoral.

The Nasal, Chin, Mid-face, Forehead, Gluteal, Calf and Pectoral are used for the areas indicated in the type names. The Block type is used for various areas during plastic and reconstruction surgeries. The Temple type can be used on a juncture where four skull bones fuse together so called the temple region.

6. Indications for Use:

MISTI Silicone Implant is intended for the augmentation or reconstruction of the nasal, malar, chin, gluteal, calf and/or pectoral contour.

7. Performance Data (Non-Clinical):

The following tests were performed on the subject device and the test results support that the subject device is substantially equivalent to the predicate devices.

- Sterilization Validation
- Appearance
- Dimensional inspection
- Extraction
- Hardness (ASTM D2240 (Type A))
- Tensile strength (ASTM D412)
- Elongation (ASTM D412)
- Tear strength (ASTM D624)
- Cytotoxicity (ISO 10993-5)
- Skin Sensitization (ISO 10993-10)
- Intracutaneous Reactivity (ISO 10993-23)
- Pyrogen (ISO 10993-11)
- Acute Systemic Toxicity (ISO 10993-11)
- Subchronic Toxicity (ISO 10993-11)
- Implantation (ISO 10993-6)
- Genotoxicity (Ames) (ISO 10993-3)
- Genotoxicity (In vitro) (ISO 10993-3)

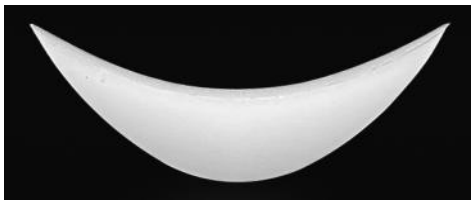
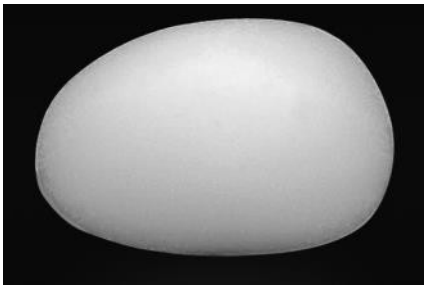
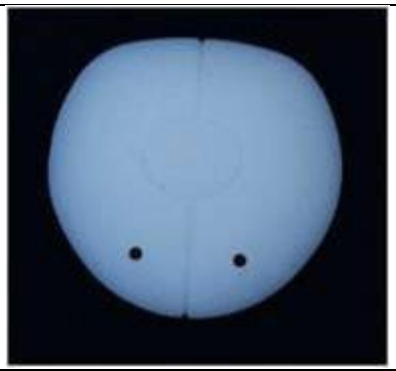
The following biocompatibility tests were not performed but the rationale for not performing them was provided.

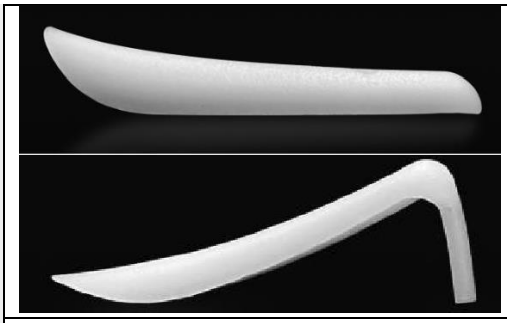
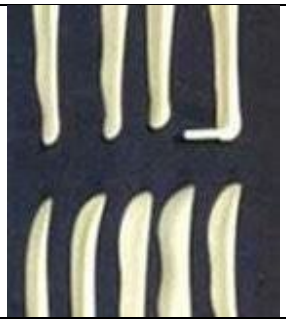
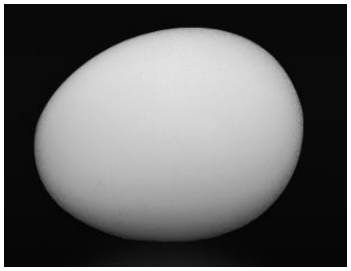
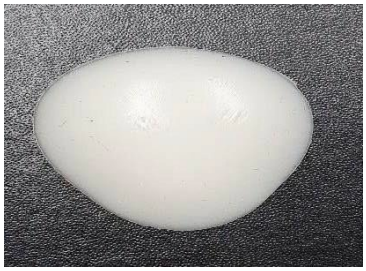
- Chronic toxicity
- Carcinogenicity

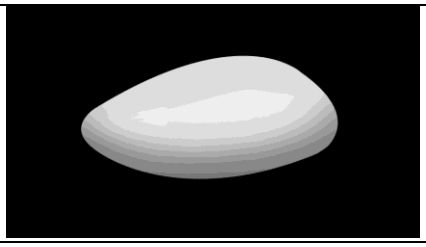
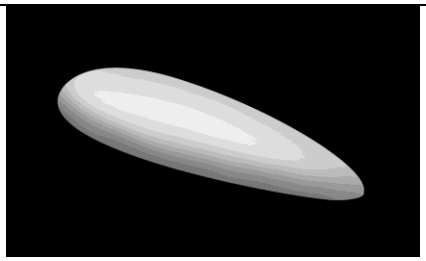
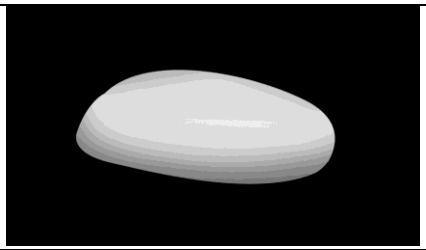
8. Substantial Equivalence

8.1. Comparison Chart

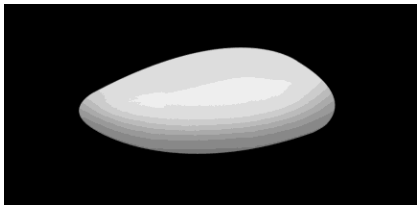
- Primary Predicate Device

	Subject Device	Primary Predicate Device
Device Name	MISTI Silicone Implant	SOFTXIL
Manufacturer	KEOSAN TRADING CO.	BISTOOL Inc.
510k #	K241150	K171851
Product Code	MIB, LZK, FWP, MIC	MIB, LZK, FWP
Indications for Use	MISTI Silicone Implant is intended for the augmentation or reconstruction of the nasal, malar, chin, gluteal, calf and/or pectoral contour.	SOFTXIL is intended for the augmentation or reconstruction of the nasal, malar, and/or chin contour.
Material	Silicone elastomer	Silicone elastomer
Design	Chin Implant	
Features		
	Mid-face Implant	
		
	Nasal Implant	

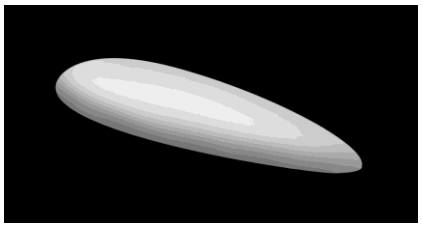
		
	Block Implant	
		
	Forehead Implant	
		
	Temple Implant	
		
	Gluteal Implant	

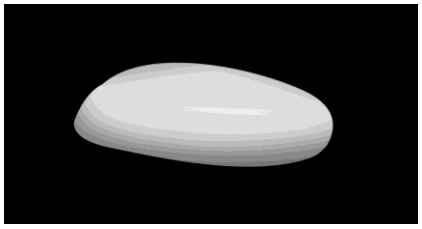
		-
	Calf Implant	
		-
	Pectoral Implant	
		-
Principle of Operation	It is made of implant grade silicone elastomer, and the design characteristic minimizes carving and promotes natural line.	It is made of implant grade silicone elastomer, and the design characteristic minimizes carving and promotes natural line.

- Reference devices

	Subject Device	Reference Device
Device Name	MISTI Silicone Implant	Gluteal Implant, models RND 5-X, TRD 6-X
Manufacturer	KEOSAN TRADING CO.	Implantech Associates, Inc.
510k #	K241150	K052504
Product Code	MIB, LZK, FWP, MIC	MIB
Indications for Use	MISTI Silicone Implant is intended for the augmentation or reconstruction of the nasal, malar, chin, gluteal, calf and/or pectoral contour.	The Gluteal Implants (Silicone Carving Blocks) are for augmentation and reconstructive surgery. The Implantech Gluteal Implants are carvable to allow the surgeon to shape the device should additional shaping be desired.
Material	Silicone elastomer	Silicone elastomer
Design Features	Gluteal Implant	
		

	Subject Device	Reference Device
Device Name	MISTI Silicone Implant	Calf Implant, model EC17-X
Manufacturer	KEOSAN TRADING CO.	Implantech Associates, Inc.
510k #	K241150	K052505
Product Code	MIB, LZK, FWP, MIC	MIB
Indications for Use	MISTI Silicone Implant is intended for the augmentation or reconstruction of the nasal, malar, chin, gluteal, calf and/or pectoral contour.	The Calf Implants (Silicone Carving Blocks) are for augmentation and reconstructive surgery. The Implantech Calf Implants are carvable to allow the surgeon to shape the device should additional shaping be desired.
Material	Silicone elastomer	Silicone elastomer
Design	Calf Implant	

Features		

	Subject Device	**Reference Device**
Device Name	MISTI Silicone Implant	Pectoralis Implant
Manufacturer	KEOSAN TRADING CO.	Spirit Ridge Technologies
510k #	K241150	K952708
Product Code	MIB, LZK, FWP, MIC	FZE, FWP, LZK, MIB, MIC
Indications for Use	MISTI Silicone Implant is intended for the augmentation or reconstruction of the nasal, malar, chin, gluteal, calf and/or pectoral contour.	-
Material	Silicone elastomer	Silicone elastomer
Design Features	Pectoral Implant	
		

	Subject Device	**Reference Device**
Device Name	MISTI Silicone Implant	Customized Contour Implant
Manufacturer	KEOSAN TRADING CO.	Implantech Associates, Inc.
510k #	K241150	K200610
Product Code	MIB, LZK, FWP, MIC	FWP, KKY, MIB, MIC

Indications for Use	MISTI Silicone Implant is intended for the augmentation or reconstruction of the nasal, malar, chin, gluteal, calf and/or pectoral contour.	The Customized Contour Implant is intended for augmentation, reconstructive and cosmetic surgery. The Customized Contour Implant is pre-shaped to the surgeon's specification to meet the needs of a particular patient, for example facial implants, gluteal implants, calf implants, or pectoralis implants.
Material	Silicone elastomer	Silicone elastomer

8.2. Substantial Equivalence Discussion

The MISTI Silicone Implant is substantially equivalent in material, design, function, and performance to predicate devices. We identified the reference devices for different areas to be used on patients.
All products have identical intended uses and are offered in similar shapes and sizes. The size might be different between the devices, however, since the physician can carve or cut the material to fit each patient so that this difference does not raise an issue of safety and performance.
We have performed the performance and biocompatibility tests and the test results support that the subject device is substantially equivalent to the predicate devices in the market.

9. Conclusion:

Based on the information submitted herein, KEOSAN TRADING CO. concludes that the MISTI Silicone Implant is substantially equivalent to the predicate device.