

510(k) Summary

(K241150)

Date: July 24, 2024

1. Applicant / Submitter:

KEOSAN TRADING CO.
#805, #806, Human Teco B/D, 57, Ahasan-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)

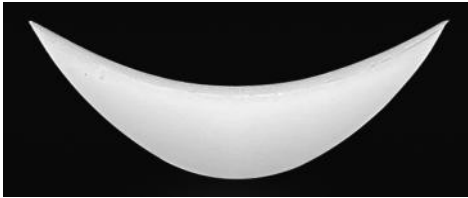
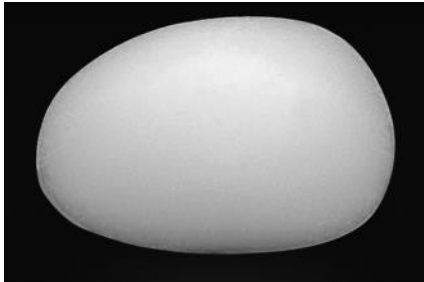
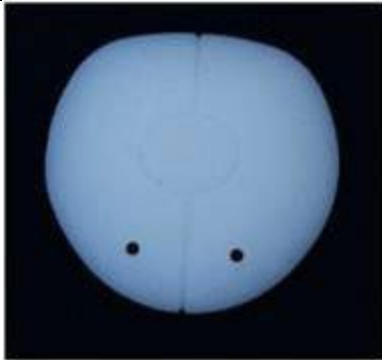
The following biocompatibility tests were not performed but the rationale for not performing them was provided.

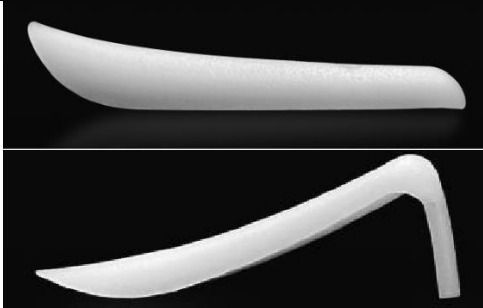
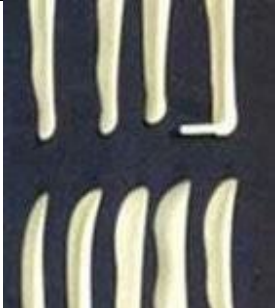
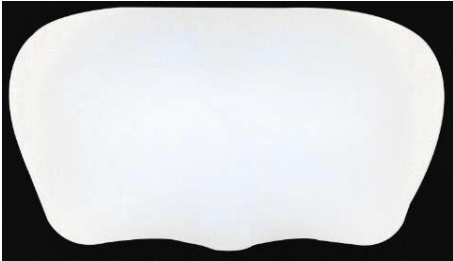
- Chronic toxicity
- Carcinogenicity

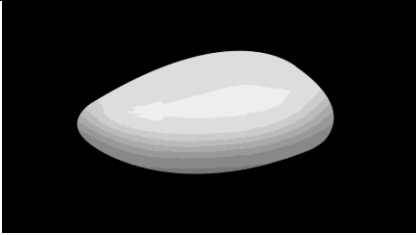
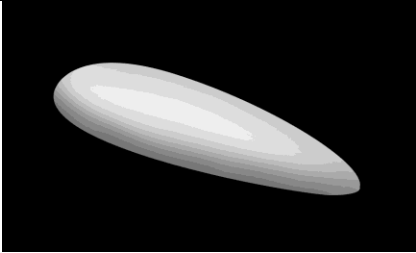
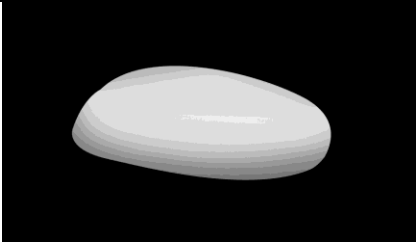
8. Substantial Equivalence

8.1. Comparison Chart

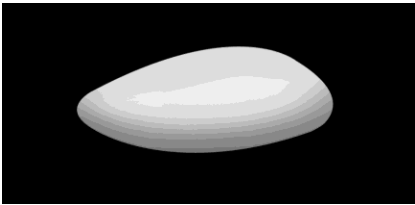
- Primary Predicate Device

	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	

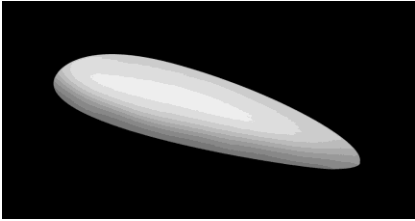
		
	Block Implant	
		
	Forehead Implant	
		
	Temple Implant	
		
	Gluteal Implant	

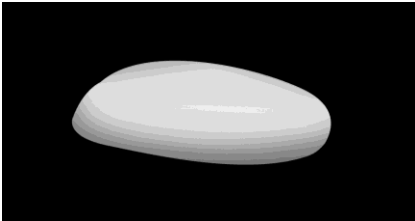
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	Calf Implant	
		-
	Pectoral Implant	
		-
Principle of Operation	It is made of implant grade silicone elastomer, and the design characteristic minimizes carving and promotes natural line.	It is made of implant grade silicone elastomer, and the design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