November 22, 2023

KEOSAN TRADING CO.
% Priscilla Chung
LK Consulting Group USA, Inc.
18881 Von Karman Ave. STE 160
Irvine, CA 92612

Re: K232593
Trade/Device Name: FITme Customized Silicone Implant
Regulation Number: 21 CFR 878.3550
Regulation Name: Chin Prosthesis
Regulatory Class: Class II
Product Code: FWP, KKY
Received: August 26, 2023

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,

Tek N. Lamichhane -S

Digitally signed by Tek N. Lamichhane -S
Date: 2023.11.22 08:44:36 -05'00'

Tek N. Lamichhane, Ph.D.
Assistant Director
DHT4B: Division of Infection Control
and Plastic and Reconstructive Surgery Devices
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and Infection Control Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K232539

Device Name
FITme Customized Silicone Implant

Indications for Use *(Describe)*

The FITme Customized Silicone Implant is intended for augmentation, reconstructive and cosmetic surgery of the facial regions.
The FITme Customized Silicone Implant is pre-shaped to the surgeon's specification to meet the needs of a particular patient.

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

K232593

Date Prepared: Nov 20, 2023

1. Applicant / Submitter:

KEOSAN TRADING CO.
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Seongdong-gu, Seoul, Republic of Korea
Tel : +82-2-466-1188

2. Submission Correspondent:

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18881 Von Karman Ave STE 160
Irvine CA 92620
Phone: 714-202-5789 Fax: 714-409-3357
Email: juhee.c@lkconsultinggroup.com

3. Device Information:

Proprietary Name:	FITme Customized Silicone Implant
Common Name:	Silicone Implant
Device Class:	II
Primary Product Code & Regulation:	FWP (21CFR§878.3550 - Prosthesis, Chin, Internal)
Secondary Product Code & Regulation:	KKY (21CFR§878.3500 - Material, Polytetrafluoroethylene Vitreous Carbon, For Maxillofacial Reconstruction

4. Predicate Device:

Customized Contour Implant (K191130) by Implantech Associates Inc.
(21CFR§878.3550, Product Code: FWP, 21CFR§878.3500, Product Code: KKY)

5. Device Description:

The FITme Customized Silicone Implant is a patient-specific medical device intended for augmentation, reconstructive and cosmetic surgery of facial region, specifically the nasal contour, the malar cheek contour, and chin contour. The device is a single use implant intended for long term implantation as a space occupying device to form a contoured feature. The customized implant, FITme Customized Silicone Implant, is made of implant grade silicone elastomer, in a range of durometers as specified by the surgeon.

The patient's own medical imaging (e.g., Computed Tomography (CT) scan) is translated into a digital model of the patient's skull using the software, Mimics by Materialise. At the recommendation of the surgeon, the Mimics is used either to 3D-print a skull model for the surgeon to fashion a solid implant model with commercially available plaster or to create a digital implant model as an STL file.
KEOSAN TRADING Co. manufactures the customized molds from the solid implant model provided by the surgeon, or the digital implant model provided by KEOSAN TRADING Co., using plaster molds or 3D-printed molds as appropriate. The FITme Customized Silicone Implant is manufactured from the customized molds and provided to the surgeon, non-sterile.

6. Indications for Use:

The FITme Customized Silicone Implant is intended for augmentation, reconstructive and cosmetic surgery of the facial regions.
The FITme Customized Silicone Implant is pre-shaped to the surgeon's specification to meet the needs of a particular patient.

7. Substantial Equivalence

7.1. Comparison Chart

	Subject Device	Predicate Device
Device Name	FITme Customized Silicone Implant	Customized Contour Implant
Manufacturer	KEOSAN TRADING CO.	Implantech Associates Inc.
510k #	K232539	K191130
Product Code	FWP, KKY	FWP, KKY
Indications for Use	The FITme Customized Silicone Implant is intended for augmentation, reconstructive and cosmetic surgery of the facial regions. The FITme Customized Silicone Implant is pre-shaped to the surgeon's specification to meet the needs of a particular patient.	The Customized Contour Implant is intended for augmentation, reconstructive and cosmetic surgery of the facial regions. The Customized Contour Implant is pre-shaped to the surgeon's specification to meet the needs of a particular patient.
Material	Silicone elastomer	Silicone elastomer
Design Features	Chin Implant	
	Malar Implant	
	Nasal 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.
Technological Characteristics	Use of 3D printing technology to create patient-specific molds and implant models derived from CT scans of a patient	Use of 3D printing technology to create patient-specific molds and implant models derived from CT scans of a patient
Additive Manufacturing Process	Surgeon's specification-> Input (solid model or digital file) -> Mold Creation (plaster mold or 3D printed mold) -> Customized Implant	Surgeon's specification-> Input (solid model or digital file) -> Mold Creation (plaster mold or 3D printed mold) -> Customized Implant

7.2. Substantial Equivalence Discussion

The FITme Customized Silicone Implant is substantially equivalent in material, design, function, and additive manufacturing process to predicate devices. 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 device in the market.

8. 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
- Biocompatibility Tests in accordance with ISO 10993
- Hardness Test in accordance with ASTM D2240
- Tensile Strength Test in accordance with ASTM D412
- Elongation in accordance with ASTM D412
- Tear Strength Test in accordance with ASTM D624
- 3D Printer Validation

9. Conclusion:

Based on the information submitted herein, KEOSAN TRADING CO. concludes that the FITme Customized Silicone Implant is substantially equivalent to the predicate device, Customized Contour Implant (K191130).