August 23, 2019

Implantech Associates Inc.
% Pierre Bounaud, Ph.D.
Senior Consultant
AcKnowledge Regulatory Strategies
2251 San Diego Ave, Suite B-257
San Diego, California 92110

Re: K191130
Trade/Device Name: Customized Contour Implant
Regulation Number: 21 CFR 878.3550
Regulation Name: Chin prosthesis
Regulatory Class: Class II
Product Code: FWP, KKY
Dated: April 25, 2019
Received: June 5, 2019

Dear Dr. Bounaud:

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,

For David Krause, Ph.D.
Acting Division Director
Division of Infection Control and Plastic Surgery Devices
Office of Surgical 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191130

Device Name
Customized Contour Implant

Indications for Use *(Describe)*
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.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary
K191130

DATE PREPARED
August 2, 2019

MANUFACTURER AND 510(k) OWNER
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DEVICE INFORMATION

Proprietary Name/Trade Name:	Customized Contour Implant
Common Name:	Elastomer, Silicone Block
Regulation Number:	21 CFR 878.3550
Class:	II
Product Code:	FWP, KKY
Review Panel:	General and Plastic Surgery

PREDICATE DEVICE IDENTIFICATION
The 3D Accuscan Facial Contour Implant is substantially equivalent to the following predicate:

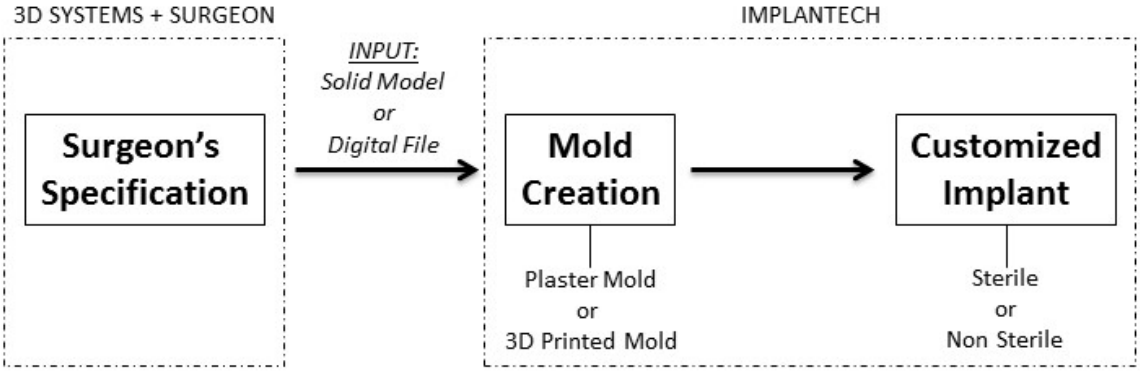
510(k) Number	*Predicate Device Name / Manufacturer*	*Primary Predicate*
K913761	3-D Accuscan Facial Implants / Implantech Associates	✓

The predicate device has not been subject to a design related recall.

DEVICE DESCRIPTION
The Customized Contour Implant is a patient-matched device intended for augmentation, reconstructive and cosmetic surgery of the facial regions, specifically the nasal contour, the malar cheek contour, and the 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 is made of medical grade silicone elastomer, in a range of durometers as specified by the surgeon.

The patient's own medical imaging (e.g., Computerized Tomography (CT) scan) is translated into a digital model of the patient's skull using VSP® Software from 3D Systems. At the recommendation of the surgeon, the VSP® Software is used either to 3D-print a skull model for the surgeon to fashion a solid implant model with commercially available plaster or silicon kits, or to create a digital implant model as an STL file. Implantech Associates manufactures the customized molds from the solid implant model provided by the surgeon, or the digital implant model provided by 3D Systems, using plaster molds or 3D-printed molds as appropriate. The Customized Contour Implant is manufactured from the customized molds and provided to the surgeon, sterile or non-sterile.



INDICATIONS FOR USE

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.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

The subject device has the same intended use, target population, design, and materials as the device cleared in K913761.

Unlike the predicate device cleared in K913761, manufacturing of the Customized Contour Implant includes two additional routes involving the use of 3D printing technology to create patient-specific molds and implant models derived from CT scans of a patient. VSP® Software by 3D Systems provides the transfer of the patient's medical imaging to a digital format appropriate for 3D printing of patient-specific molds and implant models.

SUMMARY OF NON-CLINICAL TESTING

No FDA performance standards have been established for the Customized Contour Implant. The following non-clinical tests were performed in order to demonstrate safety based on current industry standards:

- Sterilization validation per ISO 17655-1 and ANSI/AAMI/ISO 20857
- Packaging validation per ISO 11607
- Shelf life validation with accelerated and real time aging studies
- Cytotoxicity testing per ISO 10993-5
- Bacterial endotoxins testing per ANSI/AAMI ST72
- 3D printer validation: Fortus 360MC 3D Printer and its ancillary equipment were validated to accurately print a 3D image of a predetermined shape (1 inch cube, 1 inch diameter sphere) using STL file inputs. STL file creation using the VSP® software was validated prior to the 3D printer validation.

The results of these tests indicate that the Customized Contour Implant is substantially equivalent to the predicate device.

CONCLUSION

Based on the testing performed, including bioburden testing, cytotoxicity testing, and physicochemical testing, it can be concluded that the subject device does not raise different questions of safety or effectiveness when compared to the predicate device. The similar indications for use and technological characteristics for the proposed Customized Contour Implant are assessed to be substantially equivalent to the predicate device.