December 23, 2020

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

Re: K200610
Trade/Device Name: Customized Contour Implant
Regulation Number: 21 CFR 878.3550
Regulation Name: Chin Prosthesis
Regulatory Class: Class II
Product Code: FWP, KKY, MIB, MIC
Dated: March 5, 2020
Received: March 9, 2020

Dear Mr. 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); 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,

Cindy Chowdhury, Ph.D., M.B.A.
Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: 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)*
K200610

Device Name
Customized Contour Implant

Indications for Use *(Describe)*
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.

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

510(k) Summary

DATE PREPARED
March 5, 2020

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DEVICE INFORMATION

Trade Name/Proprietary Name	Customized Contour Implant
Common Name	Elastomer, Silicone Block

Classification Name	Classification Regulations	Device Class	Product Code
Chin prosthesis	21 CFR 878.3550	II	FWP
Polytetrafluoroethylene with carbon fibers composite implant material	21 CFR 878.3500	II	KKY
Ear, nose, and throat synthetic polymer material	21 CFR 874.3620	II	MIB
		II	MIC

Premarket Review	OPEQ/OHT4/Infection Control and Plastic Surgery Devices (DHT4B)
Review Panel	General & Plastic Surgery

510(k) Summary

PREDICATE DEVICE IDENTIFICATION

The Customized Contour Implant is substantially equivalent to the following predicates:

510(k) Number	*Predicate Device Name / Manufacturer*	*Primary Predicate*
K191130	Customized Contour Implant/Implantech Associates, Inc.	✓
K052504	Gluteal Implant, Models RND 5-X, TRD 6-X/Implantech Associates, Inc.	
K052505	Calf Implant, Model EC17-X/Implantech Associates, Inc.	
K952708	Pectoralis Implant/Spirit Ridge Technologies	

The predicate devices have 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. 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.

INDICATIONS FOR USE

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.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

Implantech Associates believes that the Customized Contour Implant is substantially equivalent to the predicate devices based on the information summarized here:

The subject device has the same intended use (facial, gluteal, calf and pectoral implants for reconstructive and augmentation/cosmetic surgery) and patient population as the devices cleared in K191130 (facial implants), K052504 (gluteal implants), K052505 (calf implants), and K952708 (pectoral implants). The subject device has similar design and identical materials as the devices cleared in K191130, K052504, K052505, and K952708. Subject and predicate devices are all made from the same Nusil silicone elastomers with the same durometer range.

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

510(k) Summary

- Cytotoxicity testing per ISO 10993-5
- 3D printer validation

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

CONCLUSION

Based on the testing performed, including sterilization validation, packaging validation, shelf life validation, cytotoxicity testing, and 3D printer validation, it can be concluded that the subject device does not raise new issues of safety or effectiveness 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 devices.