July 18, 2018

Implantech Associates Inc.
% Ms. Allison Komiyama
Principal Consultant
AcKnowledge Regulatory Strategies, LLC
2834 Hawthorn St.
San Diego, California 92104

Re: K172389
Trade/Device Name: ePTFE-Coated Auricular Implant
Regulation Number: 21 CFR 878.3590
Regulation Name: Ear prosthesis
Regulatory Class: Class II
Product Code: FZD
Dated: August 2, 2017
Received: August 8, 2017

Dear Ms. Komiyama:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

Device Name
ePTFE-Coated Auricular Implant

Indications for Use *(Describe)*
The ePTFE-Coated Auricular Implant is intended for reconstruction of the external ear.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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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510(k) Summary
K172389

DATE PREPARED
July 18, 2018

MANUFACTURER AND 510(k) OWNER
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PROPRIETARY NAME OF SUBJECT DEVICE
ePTFE-Coated Auricular Implant

COMMON NAME
Prosthesis, Ear, External

DEVICE CLASSIFICATION
Ear Prosthesis
(21 CFR 878.3590, Product Code FZD, Class II)

PREMARKET REVIEW
ODE/DSD/Plastic Surgery Devices Branch One (PRSB1)
General & Plastic Surgery

INDICATIONS FOR USE
The ePTFE-Coated Auricular Implant is intended for reconstruction of the external ear.

DEVICE DESCRIPTION
The ePTFE-Coated Auricular Implant is intended for reconstruction of the external ear. It is intended to be a long term, single use implant. Implantation of the device by the surgeon produces a contour to reconstruct the patient's outer ear feature. A surgically created "pocket" at the implantation site is made by the surgeon for placement of the device (typically placed on the skeletal feature below the soft muscle tissue). The ePTFE-Coated Auricular Implant is composed of a silicone elastomer core with an outer layer of ePTFE (expanded polytetrafluoroethylene) and is shaped approximately to that of the external ear. The implant

comes in nine sizes and the surgeon has the option to trim the implant to fit the patient's need. The implant is provided sterile or non-sterile, as either the "Left" or "Right" side.

PREDICATE DEVICE IDENTIFICATION

The ePTFE-Coated Auricular Implant is substantially equivalent to the following predicates:

510(k) Number	*Predicate Device Name / Manufacturer*	*Primary Predicate*
K863939	Porex Ear Prosthesis / Porex Medical	
K141027	Implantech ePTFE Facial Implants / Implantech Associates	
K002886	Implantech Composite Facial Implants / Implantech Associates	

SUMMARY OF NON-CLINICAL TESTING

No FDA performance standards have been established for the ePTFE-Coated Auricular Implant. Patient-contacting material was subjected to biocompatibility testing in compliance to ISO 10993-1 *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process.* Testing included cytotoxicity, irritation, sensitization, acute systemic toxicity, material-mediated pyrogenicity, implantation, and chemical characterization.

Bond strength between the silicone elastomer and the ePTFE outer layer was evaluated to confirm that the effects of aging, repetitive sterilization (dry heat and steam) and the white pigment in the silicone elastomer do not adversely affect the silicone/ePTFE mechanical bond of the ear implant.

EQUIVALENCE TO PREDICATE DEVICES

Implantech believes that the ePTFE-Coated Auricular Implant is substantially equivalent to the predicate devices based on the information summarized here:

The subject device has the same intended use and target population as the Porex Ear Prosthesis device cleared in K863939. The subject device uses similar or identical materials and similar manufacturing processes as the Implantech ePTFE Facial Implants cleared in K141027 and the Implantech Composite Facial Implants cleared in K002886. The main differences in design between the Porex Ear Prosthesis and the subject device include:

- Two-piece design vs one-piece design
- Open framework vs trimmable single-piece design
- High density propylene vs ePTFE/silicone composite

CONCLUSION

The ePTFE-Coated Auricular Implant is considered substantially equivalent to the predicate devices based on the identical indications for use, and similar technological characteristics. Based on the testing performed on the patient-contacting material, it can be concluded that the subject device does not raise new issues of safety or efficacy compared to the predicate devices.