December 27, 2017

Anatomics Pty Ltd
% Nicholas Connell, Consultant
Brandwood Biomedical
Level 8, 1 Chandos St
St Leonards, NSW 2065
Australia

Re: K171037
Trade/Device Name: PoreStar Patient Specific Implant
Regulation Number: 21 CFR 874.3620
Regulation Name: Ear, Nose, And Throat Synthetic Polymer Material
Regulatory Class: Class II
Product Code: JOF, GWO
Dated: November 28, 2017
Received: December 1, 2017

Dear Nicholas Connell:

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,

Srinivas Nandkumar -S

for Malvina Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose,
and Throat 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K171037

Device Name
PoreStar Patient Specific Implant

Indications for Use *(Describe)*
The PoreStar Patient Specific Implant is intended for the augmentation or restoration of bony contour in craniofacial defects.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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

Date Prepared: 25 December 2017

510(k) Owner: Anatomics Pty
23-27 Wellington Street,
St Kilda, VIC 3182
Australia
Tel: +61 (0) 3 9529 8088

Application Contact Nicholas Connell
Level 8, 1 Chandos St
St Leonards NSW 2065
Australia
Tel: +61(0) 299062984
Fax: +61(0) 285804613

Trade Name: PoreStar Patient Specific Implant

Common Name: Porous Polyethylene Implants

Classification Name: 21 CFR 874.3620

Product Code: JOF, GWO

Predicate Device: MEDPOR Customized Surgical Implant (K083621)

Indications for Use: The PoreStar Patient Specific Implant is intended for the augmentation or restoration of bony contour in craniofacial defects.

Device Description: The PoreStar Patient Specific Implants are a range of anatomically shaped, patient specific surgical implants manufactured from high density polyethylene (HDPE) to the reconstructive boundaries indicated by the surgeon. The interconnecting porous ("Pore-") architecture created from a star ("-Star") shaped particle resembles trabecular bone and permits tissue ingrowth into the implant. PoreStar Patient Specific Implants are individually designed from 3D Computed Tomography (CT) scans provided to Anatomics by the referring surgeon. The PoreStar Patient Specific Implants are provided sterile and intended for single-use.

Non-Clinical Testing: All non-clinical testing relating to the PoreStar Patient Specific Implant device is summarised in the table below

Characteristic	Testing
Material Safety	Biocompatibility testing of material in accordance with ISO 10993-1 • Systemic toxicity testing according to ISO 10993-11 • Genotoxicity testing according to ISO 10993-3 • Cytotoxicity testing according to ISO 10993-5 • Implantation testing according to ISO 10993-6 • Intracutaneous reactivity testing according to BS EN ISO 10993-10 • Skin sensitization testing according to ISO 10993-10
Mechanical Integrity	Tensile testing according to ASTM D638
	Flexural testing according to ASTM D790
	Screw Pull-out testing in accordance to ASTM F543
Compatibility	Verification testing of PoreStar's mechanical compatibility with screws or other fixation methods
Sterilization	Sterilization validations were performed in accordance with ISO 11135- 1 and 11737-1

	EO residuals testing per ISO 10993-7
Shelf-life	Packaging shelf-life testing on accelerated aged samples as per ASTM F1980-07 consisting of: • Peel testing to ASTM F88-09 • Dye-testing to ASTM F1929-98 and ASTM1929-12
	Mechanical characterization of aged implants consisting of: • Tensile testing according to ASTM D638 • Flexural testing according to ASTM D790 • Screw Pull-out testing according to ASTM F543
Packaging	Peel testing according to ASTM F88-15
	Dye testing according to ASTM F1929-15
	Bubble emission testing according to ASTM F2096-11
	Transport simulation test stipulated in ISTA 2A. Includes: • Compression • Vibration (fixed and random displacement) • Shock

Summary of Equivalence:

Characteristic	MEDPOR Customized Surgical Implant	PoreStar Patient Specific Implant	Comment
Intended Use	The MEDPOR Customized Surgical Implant is intended for the augmentation or restoration of bony contour in craniofacial defects.	The PoreStar Patient Specific Implant is intended for the augmentation or restoration of bony contour in craniofacial defects.	Same
Prescription/ OTC	Prescription - sale by or on the order of a physician	Prescription - sale by or on the order of a physician	Same
Materials	Porous, high density polyethylene	Porous, high density polyethylene with stabilizing additives	Equivalent - the presence of additives in the material's formulation has no impact on the safety or efficacy of the device. The biocompatibility of the PoreStar Patient Specific Implant has been fully assessed according to the requirements of ISO 10993-1 (Section 16) and its mechanical characteristics have been assessed to be equivalent to the predicate (Section 19).
Size Range/ Specifications	Patient specific implants created based on patient CT scans and approved by prescribing physician	Patient specific implants created based on patient CT scans and approved by prescribing physician	Same
Packaging	Double-peel pouched and put in a clamshell or shelf box	Double peel pouched and put in a shelf box	Same
Sterile/Non-Sterile	Sterile	Sterile	Same
Sterilization Method	EO Gas	EO Gas	Same

Shelf-Life	10 Years	2 Years	Equivalent - no safety or efficacy impact as this mode of use is stipulated in the product labeling

Conclusion: The predicate and proposed devices share the same indications for use, usage environments and general principle of operation. Both devices are single patient, single-use devices which are supplied sterile. The technical characteristics are equivalent between the Anatomics PoreStar Patient Specific Implants and the Predicate device and include:

- Both devices are manufactured from high density porous polyethylene
- Both devices have the same design method whereby the implants are manufactured to the specifications set by the surgeon via submission of CT scan
- Both devices utilise plates and screws as the method of fixation
- Both devices have the same sterilization method

The primary differences between the devices are:

- The addition of small quantities of proprietary additives in the formulation of the PoreStar Patient Specific Implant's HDPE
- A validated shelf-life of 2 years for the proposed device, compared with 10 years for the predicate device.

These differences raise no issues regarding the safety or effectiveness of the proposed device and have been documented and validated in this submission.

On the basis of these similarities in design and performance, it can be established the proposed device is substantially equivalent to the predicate.