June 2, 2020

Anatomics Pty, Ltd.
℅ Christine Scifert
Partner
MRC Global
9085 East Mineral Circle, Suite 110
Centennial, CO 80112

Re: K200532
Trade/Device Name: StarPore™
Regulation Number: 21 CFR 874.3620
Regulation Name: Ear, Nose, And Throat Synthetic Polymer Material
Regulatory Class: Class II
Product Code: JOF
Dated: March 3, 2020
Received: March 4, 2020

Dear Christine Scifert:

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,

for Michael J. Ryan
Director
DHT1C: Division of ENT, Sleep Disordered Breathing, Respiratory and Anesthesia Devices
OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental 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)*
K200532

Device Name
StarPore™

Indications for Use *(Describe)*
StarPore™ implants are intended for the restoration or augmentation 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.

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510(k) Summary
StarPore™
June 1, 2020

Company: Anatomics Pty Ltd
Warehouse 1, 246 East Boundary Road,
Bentleigh East, VIC 3165, Australia
Telephone: +0011 61 3 9529 8088
Fax: +0011 61 3 9529 8099

Primary Contact: Christine Scifert
Phone: (901) 831-8053

Company Contact: Robert Thompson
VP Product Innovation
E-Mail: Robert.thompson@anatomics.com

Trade Name: StarPore™

Common Name: Polymer, Ent Synthetic, Porous Polyethylene

Plate, Cranioplasty, Preformed, Alterable

Classification: Class II

Regulation Number: 21 CFR 874.3620 (Ear, Nose, and Throat Synthetic Polymer Material)

Panel: Ear, Nose, and Throat

Product Code: JOF

Predicate Device:

- Anatomics Pty Ltd. PoreStar Patient Specific Implant – K171037

Reference Devices:

- Porex MEDPOR Surg Implant Material: Prefor Cran/Fac Impla - K922489
- Porex MEDPOR Plus Surgical Biomaterial - K012350
- Porex MEDPOR Pterional Surgical Implant - K002586

K922489 and K012350 provide reference devices that have previously been cleared with pre-formed shapes for craniofacial defects. The geometries of the subject implants are similar to the reference devices previously cleared under K922489 and K002586 for craniofacial defects.

Device Description:
StarPore™ (previously cleared as PoreStar™ Patient Specific Implants) is a range of anatomically shaped surgical implants manufactured from porous high-density polyethylene (HDPE). The star ("Star-") shaped particles create an interconnecting porous ("-Pore") architecture resembling trabecular bone. The implants are provided sterile and intended for single-use. StarPore™ is manufactured from medical grade HDPE (an electrically nonconductive and nonmagnetic polymer) and is suitable for use during Magnetic Resonance Imaging (MRI).

The purpose of this Traditional 510(k) submission is to add "off-the-shelf" implant options to the StarPore™ product line. These off-the-shelf implants would provide surgeons the options of various sizes of implants which, unlike the predicate, would not be individually designed from 3D Computed

Tomography (CT) scans provided to Anatomics by the referring surgeon. Instead, the subject implants would be offered in various off-the-shelf sizes and shapes which could then be cut by the prescribing surgeon intra-operatively to create an anatomically matched patient specific design.

StarPore™ is intended for single use only and is provided sterile, using ethylene oxide gas.

Indications for Use:
StarPore™ implants are intended for the restoration or augmentation of bony contour in craniofacial defects.

Technological Characteristics Summary:
The subject device is substantially equivalent to the following predicate:
Anatomics Pty Ltd. PoreStar Patient Specific Implant – K171037 (S.E. 12/27/2017)

The subject and predicate devices are similar in Intended Use, Technological Characteristics, Performance Specifications, and Material. See the table below for details on comparison between the subject and predicate devices:

Characteristic	StarPore™ (New Device)	PoreStar Patient Specific Implant (K171037)
Intended Use	StarPore™ implants are intended for the restoration or augmentation of bony contour in craniofacial defects.	The PoreStar Patient Specific Implant is intended for the augmentation or restoration of bony contour in craniofacial defects.
Material	Medical grade, HDPE (high density polyethylene)	Medical grade, HDPE (high density polyethylene)
Dimensions	Various shapes consisting of lengths 27mm – 80mm, widths 27mm – 110mm, and thicknesses/heights 1mm – 8mm to be further cut by prescribing surgeons intraoperatively to achieve best fit.	Patient specific implants created based on patient CT scans and approved by prescribing physician
Packaging	Double steri-pouch and put in shelf box	Double peel pouched and put in a shelf box
Sterility	Sterile, by Ethylene Oxide gas	Sterile, by Ethylene Oxide gas

Performance Testing Summary:
Previous design validation and verification activities were performed for the PoreStar™ (renamed StarPore™) implants. A new risk analysis assessment for the subject products and design specifications has been performed and show no new worst case has been introduced. Therefore, all previous testing including validation of specifications related to material properties, sterilization, biocompatibility, shelf-life, stability, and material properties are applicable to the subject device. Thus, it has been determined that no further performance testing is needed.

Substantial Equivalence Conclusions:
In conclusion, the subject StarPore™ device is similar to the predicate device in intended use, technological characteristics, material, and performance. No new questions of safety and effectiveness have been raised. Therefore, the subject device can be considered substantially equivalent.