DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

September 27, 2016

Ceremed, Inc.
Ms. Chelsea Mitchell
Vice President of Regulatory Affairs
3643 Lenawee Avenue
Los Angeles, California 90016

Re: K161446
Trade/Device Name: Biopor Porous Polyethylene Implants
Regulation Number: 21 CFR 882.5320
Regulation Name: Preformed Alterable Cranioplasty Plate
Regulatory Class: Class II
Product Code: GWO
Dated: August 2, 2016
Received: August 26, 2016

Dear Ms. Mitchell:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carlos L. Pena -S

Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine 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)*
K161446

Device Name
Biopor Porous Polyethylene Implants

Indications for Use *(Describe)*
Biopor Porous Polyethylene Implants in sheet configurations are intended for the augmentation or reconstruction of the craniofacial skeleton, including the cranial skeleton, orbit, nasal bones and the zygoma.

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:

Submitted by:

Chelsea Mitchell
Ceremed, Inc.
3643 Lenawee Ave.
Los Angeles, California 90016
Tel: (424) 258-1888
Fax: (310) 815-2130

Contact Person:	Chelsea Mitchell
Date Prepared	September 27, 2016
Common/Usual Name:	Porous High Density Polyethylene (HDPE) Surgical Implant
Proprietary Name:	Biopor® Porous Polyethylene Implants
Classification Name:	Plate, Cranioplasty, Preformed, Alterable (21 CFR 882.5320)
Product Code:	GWO

Predicate Device:

1. Ceremed, Inc. Biopor® Porous Polyethylene Surgical Implants (K141880)

Description of the device:
Biopor® Porous Polyethylene Implants are manufactured of porous high-density polyethylene (PPE), a biomaterial that is contoured or carved to suit the anatomical and functional requirements of the patient. The implants are manufactured with the option of a coating with a water-soluble alkylene oxide copolymer blend (AOC). Biopor® Porous Polyethylene Implants are provided STERILE and must not be resterilized.

Intended use (Indications For Use):
Biopor® Porous Polyethylene Implants in sheet configurations are intended for the augmentation or reconstruction of the craniofacial skeleton, including the cranial skeleton, orbit, nasal bones and the zygoma.

Comparison of Technology to Predicate Device:
The differences and similarities in technological characteristics and intended use between the subject and predicate devices are listed below:

	Biopor® PPE	Biopor® PPE
510k Number	K161446	K141880
Indications for Use Statement	Biopor® Porous Polyethylene Implants in sheet configurations are intended for the augmentation or reconstruction of the craniofacial skeleton, including the cranial skeleton, orbit, nasal bones and the zygoma.	Biopor® Porous Polyethylene Implants in block, sheet, and anatomical shapes are intended for the augmentation or reconstruction of the "maxillofacial skeleton".
Materials	PPE with AOC option	PPE with Titanium and AOC options
Configuration	Sheets	Sheets and anatomical shapes
Sterility	Unchanged	Sterile via electron beam irradiation
Packaging	Unchanged	Inner packet, outer Tyvek pouch

Biocompatibility and Performance Testing:
Performance testing of the Biopor® Porous Polyethylene Implants was completed. The biocompatibility profile was leveraged from testing to support K043133 (a predicate ancestor of K141880). The endotoxin specification of the device is < 2.15 EU/device. These data are applicable to Preformed Cranioplasty Plate (21 CFR 882.5320) and support the substantial equivalence of the subject device to the predicate (K141880). The test data is summarized below:

Test	Test Method Summary	Results
Cytotoxicity Study Using the End-Point Titration	An *in vitro* study of the AOC coating used dilutions of an extract on a confluent monolayer of mouse fibroblast cells.	The extract tested negative after 24, 48 and 72 hours. No cytotoxicity detected.
Murine Local Lymph Node Assay (LLNA)	A study of the AOC coating for delayed contract sensitization using the LLNA mouse model	Under the conditions of the study, the material was not considered sensitizing to the mouse.
ISO Modified Intracutaneous Solution	A study of the AOC coating for irritation and sensitization. 3 rabbits were injected into the skin and observed for 72 hrs.	The primary irritation index characterization for the test article was negligible.

USP and ISO Modified Systemic Toxicity	A study of the AOC coating for systemic toxicity. 10 mice were administered a dose of 50 ml/kg and observed for 7 days.	There was no evidence of systemic toxicity.
ISO Muscle Implantation	The AOC coating for evaluated for toxicity. Test articles were implanted into the muscle of rabbits.	After 2 weeks, the test article was classified as a non-irritant.
Genotoxicity Mouse Bone Marrow Micronucleus	The AOC coating for evaluated for genotoxicity using the mouse bone marrow micronucleus model.	The coating showed no evidence of cellular toxicity.
Genotoxicity: Bacterial Reverse Mutation	The AOC coating for evaluated for genotoxicity using Bacterial Reverse Mutation.	The coating showed no evidence of cellular toxicity.
Genotoxicity: In Vitro Chromosomal Aberration	The AOC coating for evaluated for genotoxicity using In Vitro Chromosomal Aberration.	The coating showed no evidence of cellular toxicity.
Bone Implantation Study in the Femur of the Rabbit	The AOC coating was implanted into the femurs of rabbits and evaluated after 4 and 8 weeks.	The test article was absorbed and all sites were healing normally.
AOC Polymer Hemolysis	The AOC coating for evaluated for hemolysis using In Vitro rabbit red blood cells.	The test article was non-hemolytic.
PPE Post-irradiation Cytotoxicity	An *in vitro* study of the irradiated PPE implant extract using MEM Elution.	The test articles were non-cytotoxic.
ISO Intramuscular Implantation AOC Coated & Uncoated PPE	AOC Coated & Uncoated PPE devices were implanted into rabbit muscle and histopathology was performed after 1, 2 and 4 weeks.	Fibrovascular ingrowth occurred into coated and uncoated implants.
Pyrogen Test in NZW Rabbits	Coated implants were evaluated for pyrogenicity in NZW rabbits per USP<151>.	No Pyrogens were detected in the device.

Suture Pull-out of AOC-Coated Biopor Porous Polyethylene Implant	Coated implants were evaluated for strength using a suture pull-out test method	The test articles met acceptance criteria.
Biopor Sheet Performance Qualification	Coated and uncoated implants were evaluated for flexibility.	The test articles met acceptance criteria.
Porosity Characterization of Porous Polyethylene Implants	Coated and uncoated implants were evaluated for porosity with the criteria of pore size greater than 40 µm.	The test articles met acceptance criteria.

Substantial Equivalence:
The Biopor® Porous Polyethylene Implants in this submission represent a line extension of additional sheet configurations intended for use in the craniofacial skeleton, and have a comparable intended use and indications for use as the predicate Biopor® Porous Polyethylene Implants indicated for use in the maxillofacial skeleton (K141880). This submission contains implants for use in the craniofacial skeleton. They are similar to one type of implants currently marketed by Ceremed.

The biocompatibility profile of the subject devices is leveraged from that of the predicate device. The mechanical properties of subject Biopor® Porous Polyethylene Implants meet the same acceptance criteria as the predicate device sheet configurations.