DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

July 14, 2016

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

Re: K160988
Trade/Device Name: Biopor®, AOC™ Porous Polyethylene, Cerepor™
Regulation Number: 21 CFR 878.3500
Regulation Name: Polytetrafluoroethylene with carbon fibers composite implant material
Regulatory Class: Class II
Product Code: KKY
Dated: June 8, 2016
Received: June 23, 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,

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)*
K160988

Device Name
Biopor Porous Polyethylene Implants

Indications for Use *(Describe)*
Biopor Porous Polyethylene Implants in block, sheet, and anatomical shapes are intended for the augmentation or reconstruction of the maxillofacial skeleton.

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 of Safety and Effectiveness

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:	March 31, 2016
Common/Usual Name:	Porous High Density Polyethylene (HDPE) Surgical Implant
Proprietary Name:	Biopor®, AOC™ Porous Polyethylene, Cerepor™
Classification Name:	Polytetrafluoroethylene with carbon fibers composite implant material
Product Code:	KKY

Predicate Devices:

1. Ceremed, Inc.
   Biopor® Porous Polyethylene Surgical Implants (K141880)
2. Poriferous, LLC
   Su-Por® Surgical Implants (K140437)
3. Stryker® (Formerly Porex)
   Medpor® Surgical Implant Material (K922489)

Description of the device:
Biopor® Porous Polyethylene Implants are manufactured of porous high-density polyethylene, a biomaterial that is easily contoured or carved to suit the anatomical and functional requirements of the patient. The interconnecting pores of the Porous HDPE material permits fibrovascular ingrowth into the implant. The implants are manufactured with the option of a coating with a water-soluble alkylene oxide copolymer blend and/or the option of embedded titanium mesh. AOC™ Porous Polyethylene Surgical Implants are provided STERILE and should not be resterilized.

Intended use (Indications):
Biopor® Porous Polyethylene Implants in block, sheet, and anatomical shapes are intended for the augmentation or reconstruction of the maxillofacial skeleton.

Substantial equivalence:
Biopor® Porous Polyethylene Implants in this application represent a line extension of additional shapes and sizes, and have the same intended use and indications for use as the predicate Biopor® Porous Polyethylene Implants (K141880). The additional shapes and sizes are equivalent to those of the predicates Medpor® Surgical Implant Material (K922489) and Su-Por® Surgical Implants (K140437).

The biocompatibility of the alkylene oxide copolymer blend is in accordance with the standards set forth in ISO 10993 Biological Testing of Medical and Dental Materials and Devices.

The mechanical properties of AOC™ Porous Polyethylene Surgical Implants are substantially equivalent to the corresponding properties of the predicate devices made of porous polyethylene, and any minor differences raise no new issues of safety and efficacy.

Biocompatibility and Performance Testing:
Performance testing of the Biopor® Porous Polyethylene Implants was completed. Biocompatibility and Implantation studies were also conducted in accordance with ISO 10993. The test data reports are listed below:

Cytotoxicity Study Using the End-Point Titration
Murine Local Lymph Node Assay (LLNA)
ISO Modified Intracutaneous Study Solution
USP and ISO Modified Systemic Toxicity Study Solution
ISO Muscle Implantation Study
Genotoxicity
- Mouse Bone Marrow Micronucleus Study
- Genotoxicity: Bacterial Reverse Mutation Study
- Genotoxicity: In Vitro Chromosomal Aberration Study

Bone Implantation Study in the Femur of the Rabbit
AOC Polymer Hemolysis
Porous Polyethylene Post-irradiation Cytotoxicity
ISO Intramuscular Implantation AOC Coated & Uncoated PPE
Pyrogen Test in NZW Rabbits
Suture Pullout from PPE