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

April 16, 2015

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

Re: K141880
Trade/Device Name: Biopor® Porous Polyethylene Implants
Regulation Number: 21 CFR 878.3500
Regulation Name: Polytetrafluoroethylene with carbon fibers composite implant material
Regulatory Class: Class II
Product Code: KKY
Dated: February 24, 2015
Received: March 6, 2015

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" (21CFR 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

V. INDICATIONS FOR USE:

510 (k) Number (if known): K141880

Device Name: Biopor® Porous Polyethylene Implants

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

Prescription Use_____X_____ OR Over-The-Counter Use _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED.)

CONCURRANCE OF CDRH, OFFICE OF DEVICE EVALUATION (ODE)

_____

Division Sign-Off

510(k) Number_____

IV. GENERAL INFORMATION:

A. DEVICE NAME:

a. Common/Usual Name: Porous High Density Polyethylene (HDPE) Surgical Implant

b. Proprietary Name: Biopor®, AOC™ Porous Polyethylene, Cerepor™, In the future other brand names may be used by individual licensees.

c. Classification Name: Polytetrafluoroethylene with carbon fibers composite implant material (per 21 CFR section 878.3500)

B. DEVICE SPONSOR:

a. Manufacturer:

Ceremed, Inc.
3643 Lenawee Ave.
Los Angeles, California 90016
Tel: (310) 815-2125
Fax: (310) 815-2130

b. Establishment Registration No: 3004961344
Owner/Operator # 9063721

c. Sterilization Sites:

Sterigenics
IBA Advanced Materials Division
San Diego, California 92121
Phone (858) 271-6330
Fax (858) 271-0957

C. CLASSIFICATION:

a. Class: II

b. Product Code: KKY

c. Panel: Surgical, Orthopedic, and Restorative Devices

D. PERFORMANCE STANDARDS: None established

E. SHELF LIFE: 5 years