K080507

VII - 510 (K) SUMMARY OF SAFETY AND EFFECTIVENESS:

APR 21 2008

Submitted by:

Tadeusz Wellisz, M.D.
Ceremed, Inc.
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Contact Person:	Tadeusz Wellisz, M.D.
Date Prepared	February 14, 2008
Common/Usual Name:	Porous High Density Polyethylene (HDPE) Surgical Implants
Proprietary Names:	AOC™ Porous Polyethylene, AOC™ Porous HDPE, AOC™ Porous Polyethylene Surgical Implant, Cerepor, PPE, PPE C, PPE Ti, PPE C-Ti, Synpor™, Synpor™ C, Synpor™ Ti, Synpor™ C-Ti, Biopor™, Biopor™ C, Biopor™ Ti, Biopor™ C-Ti
Classification Name:	Polymer ENT Synthetic, Porous Polyethylene (per 21 CFR section 874.3620)

Predicate Devices

1. Ceremed, Inc.
   AOC™ Porous Polyethylene Surgical Implants
   K043133

2. Porex Surgical Inc.
   MEDPOR® Craniofacial Implants with embedded Titanium Mesh
   K040364

Description of the device:
AOC™ Porous Polyethylene Surgical Implants are provided as blocks, sheets, and anatomical shapes, and are manufactured of porous high-density polyethylene (HDPE), a material that has been used in craniofacial reconstruction for over 25 years. 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 Implants are provided sterile by irradiation and must not be resterilized.

Intended use:
AOC™ Porous Polyethylene Surgical Implants in block, sheet, and anatomical shapes are intended for the augmentation or reconstruction of the craniomaxillofacial skeleton.

Substantial equivalence:
AOC™ Porous Polyethylene Surgical Implants have the same intended use and indications for use as the predicate devices made of porous polyethylene. 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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 21 2008

Ceremed, Inc.
% Tad Wellisz, M.D.
President
3643 Lenawee Avenue
Los Angeles, California 90016

Re: K080507
Trade/Device Name: AOC Porous Polyethylene
Regulation Number: 21 CFR 878.3500
Regulation Name: Polytetrafluoroethylene with carbon fibers composite implant material
Regulatory Class: II
Product Code: KKY
Dated: February 14, 2008
Received: March 12, 2008

Dear Dr. Wellisz:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K080507

Device Name: AOC Porous Polyethylene

Indications For Use:
AOC™ Porous Polyethylene Surgical Implants are intended for the augmentation or reconstruction of the craniomaxillofacial skeleton.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. Ogden for MKM

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K080507