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

Submitted by:

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DEC 1 1 2006

Contact Person:	Tadeusz Wellisz, M.D.
Date Prepared	November 14, 2006
Common/Usual Name:	Soluble Polymer Surgical Implant Material
Proprietary Names:	Ostene®, AOC™, Osteotene™, Ceretene™, Cerepor™, Aptene™, Apatene™, Actipaste™
Classification Name:	Synthetic Polymer Material, (per 21 CFR 874.3620)
Product Code:	KHJ, MTJ

Predicate Devices

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

2. Ceremed, Inc.
   AOC™ Bone Wax
   K041363

3. Ceremed, Inc.
   AOC™ Bone Wax (Ostene®)
   K052528

4. Genzyme Corp.
   Sepragel™ ENT
   K043035

5. Medtronic Xomed, Inc.
   MeroGel™ Injectable
   K002972

Description of the device:
Ostene® is a water-soluble odorless, opaque wax-like material consisting of a sterile mixture of alkylene oxide copolymers, derived from ethylene oxide and propylene oxide. It is best used immediately following removal from the package, and can be softened and increased in stickiness by warming and by additional handling and manipulation, if so desired. Ostene® is provided sterile by irradiation and must not be resterilized.

Intended use:
Ostene® is intended for use as a water-soluble space occupying material as an adjunct during the natural healing process and it provides for control of bleeding from bone surfaces by acting as a mechanical barrier.

Substantial equivalence:
The Ostene® in this application has the same intended use fundamental scientific technology as the legally marketed AOC™ Bone Wax (Ostene®) and the coating of AOC™ Porous Polyethylene Surgical Implants. The classification of the Ostene® as water-soluble synthetic polymer material for use as a space occupying material is supported by its comparison to the legally marketed device Sepragel (K043035) and MeroGel (K002972).

The Ostene® in this application as a bone hemostatic agent is identical to, and has the same intended use and indications for use as the predicate device AOC™ Bone Wax (Ostene®). 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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

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Re: K062280
Trade/Device Name: Ostene®, AOC™, Osteotene™, Ceretene™, Cerepor™, Aptene™, Apatene™, Actipaste™
Regulation Number: 21 CFR 874.3620
Regulation Name: Ear, nose, and throat synthetic polymer material
Regulatory Class: II
Product Code: KHJ, MTJ
Dated: November 14, 2006
Received: November 16, 2006

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 Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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

XII. INDICATIONS FOR USE:

510 (k) Number (if known): K062280

Device Name: Ostene®, AOC™, Osteotene™, Ceretene™, Cerepor™, Aptene™, Apatene™, Actipaste™

Indications For Use:
OSTENE® is indicated for use as a water-soluble implant material for use in the control of bleeding from bone surfaces and as a water-soluble space occupying material as an adjunct during the natural healing process.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Per 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)

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

510(k) Number K062280