

Ceremed, Inc.
510 (k) Premarket Notification – AOC™ Soluble Implant Material

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

Submitted by:

JUL 18 2008

Tadeusz Wellisz, M.D.
Ceremed, Inc.
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Contact Person: Tadeusz Wellisz, M.D.

Date Prepared May 23, 2008

Common/Usual Name: AOC™ Soluble Implant Material

Proprietary Names: AOC™, AOC™ Implant Material, Ceretene™, AOC™-ES, AOC™-LV

Classification Name: Ear, nose, and throat synthetic polymer material (per 21 CFR section 874.3620)

Product Code KHJ

Predicate Devices

1. Ceremed, Inc.
Ostene® Soluble Implant Material (K062280)
2. Ceremed, Inc.
AOC™ Porous Polyethylene Surgical Implants (K080507)



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

JUL 18 2008

Re: K081531

Trade/Device Name: AOC™, AOC™ Implant Material, AOC™ Soluble Implant Material,
Ceretene™, AOC™ -ES, AOC™ -LV

Regulation Number: ~~21 CFR 874.3620~~

Regulation Name: Ear, nose, and throat synthetic polymer material

Regulatory Class: II

Product Code: KHJ

Dated: May 23, 2008

Received: June 5, 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

XII. INDICATIONS FOR USE:

510 (k) Number (if known): K081531

Device Name:

AOC™, AOC™ Implant Material, AOC™ Soluble Implant Material, Ceretene™, AOC™-ES, AOC™-LV

Indications For Use:

~~AOC™ is indicated for use as a water-soluble implant material and as a water-soluble space occupying material, as an adjunct during the natural healing process.~~

Prescription Use
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 CFR 807 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

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