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

Submitted by:

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SEP 1 8 2008

Contact Person:	Tadeusz Wellisz, M.D.
Date Prepared	September 14, 2008
Common/Usual Name:	AOC™-L Soluble Implant Material
Proprietary Names:	AOC™, Ostene™, AOC™ Implant Material, Ceretene™, AOC™-LV
Regulation Number:	21 CFR section 874.3620
Regulation Name:	Synthetic polymer material
Regulatory Class	II
Product Code	KHJ
Predicate Device	Ceremed, Inc. AOC™ Soluble Implant Material (K081531)

Description of the device:
AOC™-L Soluble Implant Material is an odorless, opaque wax-like material designed to be utilized directly out of the package. 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.

AOC™-L Soluble Implant Material is comprised of a sterile aqueous mixture of water-soluble alkylene oxide copolymers, derived from ethylene oxide and propylene oxide. AOC™-L Soluble Implant Material contains no other additives or colorants. AOC™-L Soluble Implant Material is formed of various weights ranging from 0.5 to 5 grams each.

AOC™-L Soluble Implant Material is provided sterile by irradiation and must not be resterilized.

Intended use:

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

Fundamental Technology:

AOC™-L Soluble Implant Material is comprised of a sterile aqueous mixture of water-soluble alkylene oxide copolymers, derived from ethylene oxide and propylene oxide. The copolymers dissolve from the site of application, and are not metabolized, but are eliminated from the body unchanged in the urine and feces.

AOC™-L Soluble Implant Material differs from the predicate device in that water has been added to alter the handling properties of the device.

Substantial equivalence:
AOC™-L Soluble Implant Material has the same intended use fundamental scientific technology and indication for use as the legally marketed predicate, AOC™ Soluble Implant Material (K081531).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 8 2008

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

Re: K082245
Trade/Device Name: AOC™ -L Soluble Implant Material, AOC™, Oxtene™, AOC™ Implant Material, Ceretene™, AOC™ -LV
Regulation Number: 21 CFR 874.3620
Regulation Name: Ear, nose, and throat synthetic polymer material
Regulatory Class: II
Product Code: KHJ
Dated: July 28, 2008
Received: August 7, 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

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): K082245

Device Name:

AOC™-L Soluble Implant Material, AOC™, Ostene™, AOC™ Implant Material, Ceretene™, AOC™-LV

Indications For Use:

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

Prescription Use ____X____ (Per 21 CFR 801.109) OR Over-The-Counter Use _____ (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)
Division of General, Restorative, and Neurological Devices

510(k) Number K082245

Division Sign-Off

510(k) Number K082245