JUL 27 2004

K041363

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

Submitted by:

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Ceremed, Inc.
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Contact Person:	Tadeusz Wellisz, M.D.
Date Prepared	May 19, 2004
Common/Usual Name:	Bone Wax
Proprietary Name:	AOC Bone Wax
Classification Name:	Unclassified

Predicate Devices

4. Ethicon, Inc.
   Ethicon Bone Wax
   Preamendment

5. US Surgical, Inc.
   Auto Suture Bone Wax
   K971680

6. Lukens Corp.
   Lukens Bone Wax
   K791495

Description of the device:
AOC Bone Wax 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 additional handling and manipulation, if so desired. AOC Bone Wax is provided sterile by irradiation and must not be resterilized.

Used for over 100 years, bone waxes stop bone bleeding by the creation of a physical barrier along the edges of bones that have been damaged by trauma or cut during a surgical procedure. The wax, when placed on bone under moderate pressure, plugs the vascular openings in the bone. This plug prevents further bleeding.

Intended use:
AOC Bone Wax is intended for use in the control of bleeding from bone surfaces.

Substantial equivalence:

AOC Bone Wax has the same intended use and indications for use as Ethicon Bone Wax (preamendment), Lukens Bone Wax (K791495), which are manufactured from bee's wax, and Auto Suture Bone Wax (K971680), which is manufactured from a sterile mixture of glycolide, caprolactone, mannitol and ß-tricalcium phosphate.
AOC Bone Wax is comprised of a sterile mixture of water-soluble alkylene oxide copolymers, derived from ethylene oxide and propylene oxide. AOC Bone Wax contains no other additives or colorants and it is provided as sterile sticks weighing 2.5 grams each. The biocompatibility of AOC Bone Wax 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 Bone Wax are substantially equivalent to the corresponding properties of the predicate devices, 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

JUL 27 2004

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

Re: K041363
Trade/Device Name: AOC Bone Wax
Regulatory Class: Unclassified
Product Code: MTJ
Dated: May 19, 2004
Received: May 21, 2004

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 (301) 594-4659. 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
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): K041363

Device Name: AOC Bone Wax

Indications For Use:
AOC Bone Wax is indicated for use in the control of bleeding from bone surfaces.

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

Miriam C Provost

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

510(k) Number K041363