K102071

VI - 510 (K) SUMMARY

Submitted by:

OCT - 8 2010

Tadeusz Wellisz, M.D.
Ceremed, Inc.
3643 Lenawee Ave.
Los Angeles, California 90016
Tel: (310) 815-2125
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Contact Person:	Tadeusz Wellisz, M.D.
Date Prepared	October 06, 2010
Common/Usual Name:	Soluble Bone Hemostasis Implant Material
Proprietary Name:	Ostene®CT Bone Hemostasis Implant Material, AOC™CT, Osteotene™, Ceretene™
Regulatory Class:	Unclassified
Classification Name:	Wax, Bone
Product Code:	MTJ
Predicate Device:	Ceremed, Inc. Ostene®CT Soluble Bone Hemostasis Implant Material (K091636)

Description of the device:

Ostene®CT is a water-soluble surgical implant material for use in cardiothoracic surgery. Ostene®CT 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.

Ostene®CT is comprised of a sterile mixture of water-soluble alkylene oxide copolymers. Ostene®CT contains no other additives or colorants. The wax-like material is formed into sticks of various weights ranging from .5 to 5 grams each.

As a bone hemostasis agent, Ostene®CT stops 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. Ostene®CT, when placed on bone under moderate pressure, plugs the vascular openings in the bone. This plug prevents further bleeding.

Ostene®CT is provided sterile by irradiation and must not be resterilized.

Intended use:
Ostene®CT is indicated for use as a water-soluble implant material and for use in the control of bleeding from bone surfaces in cardiothoracic surgery following sternotomy.

Substantial equivalence:
The non-clinical evaluations used to determine substantial equivalence included indications, intended use, design, materials, sterilization, and performance. The comparison demonstrates that the device in this submission is substantially equivalent in indications and intended use; and is identical in design, materials, sterilization, and performance to the predicate Ostene®CT (K091636).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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

OCT - 8 2010

Re: K102071
Trade/Device Name: Ostene®CT, AOC™ CT, Osteotene™, Ceretene™
Regulatory Class: Unclassified
Product Code: MTJ
Dated: September 24, 2010
Received: September 29, 2010

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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

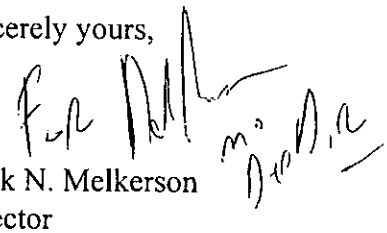
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



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

Enclosure

K102071

V. INDICATIONS FOR USE:

510 (k) Number (if known): K102071

OCT - 8 2010

Device Name: Ostene®CT, AOC™CT, Osteotene™, Ceretene™

Indications For Use:
OSTENE®CT is indicated for use as a water-soluble implant material and for use in the control of bleeding from bone surfaces in cardiothoracic surgery surgery following sternotomy.

Prescription Use_____X_____ OR Over-The-Counter Use _____
(Per 21 CFR 801.109) (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)

David Krause for MKM
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K102071

Division Sign-Off

510(k) Number_____