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

Submitted by:

Tadeusz Wellisz, M.D.
Ceremed, Inc.
3643 Lenawee Ave.
Los Angeles, California 90016
Tel: (310) 815-2125
Fax: (310) 815-2130

JUN 1 4 2005

Contact Person:	Tadeusz Wellisz, M.D.
Date Prepared	May 12, 2005
Common/Usual Name:	Bone Plate, cranioplasty preformed, non-alterable
Proprietary Names:	**Cranion™ Cranial Fixation System, FixLock™, Cranial Solutions, Ceremed™ Fixation System**
Classification Name:	Bone Plate, cranioplasty preformed, non-alterable

Predicate Devices

1. Bioplate, Inc.
   Fixation System for Craniomaxillofacial Surgery
   K023810

2. Bioplate, Inc.
   Fixation System for Craniomaxillofacial Surgery
   K021684

3. Bioplate, Inc.
   Zip Craniotomy Fixation System
   K020880

4. Bioplate, Inc.
   Bioclip Craniotomy Fixation System
   K013055

5. Bioplate, Inc.
   Zip Craniotomy Fixation System
   K013050

6. Bioplate, Inc.
   Bioclip Craniotomy Fixation System
   K011380
7. Bioplate, Inc.

Fixation System for Craniomaxillofacial Surgery
K992330

8. Bioplate, Inc.
   Fixation System for Craniomaxillofacial Surgery
   K972463

9. Bioplate, Inc.
   Fixation System for Craniomaxillofacial Surgery
   K953273

10. Bioplate, Inc.
    Fixation System for Craniomaxillofacial Surgery
    K943071

Description of the device:

The Cranion™ Cranial Fixation System includes a variety of plate configurations for different anatomical applications. Titanium alloy plates, and titanium alloy screws of varying lengths are included for fixation of the plates to the craniomaxillofacial bony tissue. Titanium alloy clamps and clips are included for the reattachment of cranial bone flaps after craniotomy procedures.

Intended use:

The Cranion™ Cranial Fixation System intended for reconstruction of the craniomaxillofacial skeleton and for reattachment of cranial bone flaps after craniotomy procedures. The system is used to align and stabilized bony tissue while normal healing occurs. Each implantable component is intended for single use only and may be combined only with other titanium and titanium alloy implants.

Substantial equivalence:

The Cranion™ Cranial Fixation System has the same indications for use as the predicate devices marketed by Bioplate, Inc. All of the technical characteristics of The Cranion™ Cranial Fixation System are substantially equivalent to the corresponding characteristics 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

JUN 14 2005

Dr. Tadeusz Wellisz
President
Ceremed, Incorporated
3643 Lenawee Avenue
Los Angeles, California 90016

Re: K051293
Trade/Device Name: Cranion™ Cranial Fixation System
Regulation Number: 872.4760
Regulation Name: Bone Plate
Regulatory Class: II
Product Code: JEY
Dated: June 2, 2005
Received: June 6, 2005

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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Janette Y. Michaud MD

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

X. INDICATIONS FOR USE:

510 (k) Number (if known): K051293

Device Name: Cranion™ Cranial Fixation System

Indications For Use:

The Cranion™ Cranial Fixation System intended for reconstruction of the craniomaxillofacial skeleton and for reattachment of cranial bone flaps after craniotomy procedures. The system is used to align and stabilized bony tissue while normal healing occurs. Each implantable component is intended for single use only and may be combined only with other titanium and titanium alloy implants.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED.)

CONCURRENCE OF CDRH, OFFICE OF DEVICE EVALUATION (ODE)

Prescription Use X OR Over-The-Counter Use _____

(Per 21 CFR 801.109) (Optional Format 1-2-96)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K051293

Division Sign-Off

510(k) Number_____