K071791

SECTION 4 510K SUMMARY

JUL 30 2007

NAME OF FIRM: Codman & Shurtleff, Inc.
325 Paramount Drive
Raynham
MA 02767-0350

510(k) CONTACT: Rachel Creane
Senior Regulatory Affairs Specialist

TRADE NAME: Cranioplastic®

COMMON NAME: Methyl Methacrylate (MMA)

CLASSIFICATION: Class II; 21 CFR 882.5300

DEVICE PRODUCT CODE: GXP

SUBSTANTIALLY EQUIVALENT DEVICES: Cranioplastic®(K873689)

SmartSet GMV Endurance Gentamicin Bone Cement (K033382).

DEVICE DESCRIPTION:

Cranioplastic® is a self-curing, methylmethacrylate (MMA) based acrylic resin, for repairing cranial defects. The following modifications are being made:

A change is being made to the formulation of the liquid and powder components of the acrylic cement and the Instructions for Use (IFU) is being updated.

INTENDED USE AND INDICATIONS:

Cranioplastic® is indicated for the repair of cranial defects.

BASIS OF SUBSTANTIAL EQUIVALENCE:

The substantial equivalence of Cranioplastic® to the identified predicate devices is demonstrated by its similarity in terms of technological characteristics (chemical composition, material properties, performance characteristics, manufacture, packaging and sterilization) to Cranioplastic® (K873689) and SmartSet GMV Endurance Gentamicin Bone Cement (K033382).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 30 2007

Codman & Shurtleff, Inc.
% Ms. Rachel Creane
Senior Regulatory Affairs Specialist
325 Paramount Drive
Raynham, MA 02767-0350

Re: K071791
Trade/Device Name: Cranioplastic®
Regulation Number: 21 CFR 882.5300
Regulation Name: Methyl methacrylate for cranioplasty
Regulatory Class: II
Product Code: GXP
Dated: June 28, 2007
Received: July 02, 2007

Dear Ms. Creane:

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) 276-0120 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 toll-free number (800) 638-2041 or (240) 276-3150 or the 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

SECTION 5 INDICATIONS STATEMENT

510(k) Number (if known):

Device Name: Cranioplastic®

Indications for Use:

Cranioplastic® is indicated for the repair of cranial defects.

Prescription Use ___X___ 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)

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

510(k) Number K071791