

K03 2388

OCT 31 2003

Cardinal Health
1500 Waukegan Road
McGaw Park, Illinois 60085-6787
847.473.1500



**510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
Bone Cement Radio-Opacifier**

Sponsor: Cardinal Health
1500 Waukegan Road - MPWM
McGaw Park, IL 60085

Contact: Sharon Nichols
Manager, Regulatory Affairs

Telephone: (847) 785-3311

Date Prepared: July, 2003

Product Trade Name: Bone Cement Radio-Opacifier

Common Name: Barium Sulfate, USP

Classification: Class II per 21 CFR §882.5300

Predicate Device: Parallax Tracer Radiopaque Particles

Intended Use: This device is used as an additive to Codman Cranioplastic (Type 1-slow set) to provide radiopacity for imaging purposes.

Substantial Equivalence: The Bone Cement Radio-Opacifier is substantially equivalent to the Parallax Tracer Radiopaque Particles in that:
- Intended use is the same
- Performance attributes are the same

Description: The Bone Cement Radio-Opacifier is an additive to be used with Codman Cranioplastic (K873689) to provide radiopacity to the resin and assist in placement and visualization of material.

Summary of testing: Based on the product performance information provided in this notification, the subject device has been shown to be substantially equivalent to the currently marketed predicate device.

Non-clinical Test Results: Performance testing demonstrated that the end product Cranioplastic and Bone Cement Radio-Opacifier is substantially equivalent to currently marketed Cranioplastic with Radio-Opacifier from Parallax with regard to functional characteristics.



OCT 31 2003

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Sharon Nichols
Regulatory Affairs Manager
Cardinal Health
1500 Waukegan Road
McGraw Park, Illinois 60085-6787

Re: K032388
Trade Name: Bone Cement Radio-Opacifier
Regulation Number: 882.5300
Regulation Name: Methyl methacrylate for cranioplasty
Regulatory Class: Class II
Product Code: MYU
Dated: July 31, 2003
Received: August 4, 2003

Dear Ms. Nichols:

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

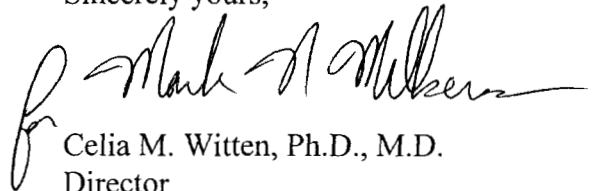
Page 2 – Ms. Sharon Nichols

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) 594-4639. 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,



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

Cardinal Health
1500 Waukegan Road
McGaw Park, Illinois 60085-6787
847.473.1500
FAX: 847.785.2461



Page 1 of 1

510(k) Number (if known):

K032388

Device Name:

Bone Cement Radio-Opacifier

Indications For Use:

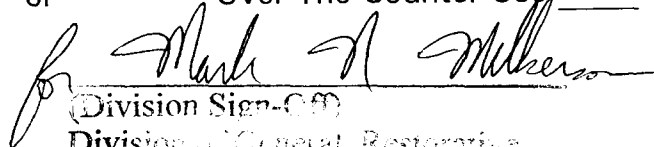
This device is used as an additive to Codman Cranioplastic (Type 1-slow set) to provide radiopacity for imaging purposes.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
(Per 21 CFR 801.109)

or Over-The Counter Use


Division Sign-Off

Division of General, Restorative
and Neurological Devices

510(k)

K032388