K032388

OCT 31 2003

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

CardinalHealth

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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 31 2003

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

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,

for Mark N. Melkerson

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

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CardinalHealth

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 ✓ or Over-The Counter Use ____
(Per 21 CFR 801.109)

for Mark N Milhern
(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(K032388