MAY 1 1 2005

K043518

Cardinal Health
1430 Waukegan Road
McGaw Park, Illinois 60085-6787
847.689.8410

CardinalHealth

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
Radiopaque Bone Cement

Sponsor:	Cardinal Health 1430 Waukegan Road McGaw Park, IL 60085
Contact:	Sharon Nichols Manager, Regulatory Affairs
Telephone:	(847) 578-6610
Date Prepared:	December, 2004
Product Trade Name:	Radiopaque Bone Cement
Common Name:	Polymethyl Methacrylate (PMMA)
Classification:	Class II per 21 CFR §882.5300
Predicate Device:	Stryker Spineplex Radiopaque Bone Cement
Intended Use:	Radiopaque Bone Cement is indicated for the fixation of pathological fractures of the vertebral body.
Substantial Equivalence:	This device is substantially equivalent to Stryker Spineplex Radiopaque Bone Cement (K032945).
Description:	Radiopaque Bone Cement is a self-curing acrylic that a surgeon uses to inject into the vertebral body of a patient with pathological fractures within a vertebral body. It is comprised of two sterile components (liquid and powder), which are mixed to form the cement.
Summary of testing:	Based on the product performance information provided to FDA, 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 proposed Radiopaque Bone Cement is substantially equivalent to currently marketed Spineplex with regard to functional characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 1 1 2005

Ms. Sharon Nichols
Regulatory Affairs Manager
Cardinal Health
1430 Waukegan Road, WM
McGaw Park, Illinois 60085

Re: K043518
Trade/Device Name: Radiopaque Bone Cement
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) bone cement
Regulatory Class: II
Product Code: NDN
Dated: April 25, 2005
Received: April 26, 2005

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 (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 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,

for Miriam Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use

510(k) Number (if known): K043518

Device Name: Radiopaque Bone Cement

Indications For Use:

Radiopaque Bone Cement is indicated for the fixation of pathological fractures of the vertebral body.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 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 K043518