K091382

510(k) Summary

NOV 16 2009

Contact: Justin Eggleton
Musculoskeletal Clinical & Regulatory Advisers, LLC
1331 H Street NW, 12th Floor
Washington, DC 20005
202.552.5800

Device Trade Name: Kryptonite Bone Cement™

Manufacturer: Doctors Research Group, Inc.
574 Heritage Road, Suite 202
Southbury, CT 06488
Telephone: (800) 371 – 2535
Fax: (203) 262 – 9340

Classification: 21 CFR §882.5300

Classification Name: Methyl methacrylate for cranioplasty

Class: II

Product Code: GXP

Indications For Use:
Kryptonite Bone Cement™ is a resinous material for repairing cranial defects.

Device Description:
Kryptonite Bone Cement™ is a resinous material to be used as a cranial bone void filler. Kryptonite Bone Cement™ is a self-setting bone cement that is formed by combining and mixing three components, resulting in a mild exothermic polymeric reaction (less than body temperature) that polymerizes into a malleable putty and progresses to a hard cement-like complex. The three components of Kryptonite Bone Cement™ are a liquid pre-polymer isocyanate mixture, a liquid polyester polyol, and a powdered calcium carbonate.

Predicate Device(s):
Kryptonite Bone Cement™ was shown to be substantially equivalent to previously cleared cranioplasty devices and has the same indications for use, design and function – including, but not limited to, Cardinal Health Bone Cement (K040152) and Biomet Craniofacial Acrylic Cement (K011399). Performance testing demonstrates Kryptonite Bone Cement has equivalent performance to the predicate devices. Please refer to the following section for more information regarding the performance comparison.

Performance Standards:

Material, biocompatibility, mechanical, and animal studies were performed to demonstrate substantial equivalence. Material characterization tests demonstrated comparable material handling properties, including exotherm, mixing time, and setting time to the cited predicates. Biocompatibility testing included the entire ISO-10993 test battery. Kryptonite Bone Cement passed all tests according to the specified acceptance criteria and/or through side-by-side testing with a predicate. Mechanical testing evaluated static and dynamic mechanical properties under physiologically relevant loading conditions. The results of these tests demonstrated mechanical properties were consistent with predicate devices. Animal studies in rabbits (e.g., calvarial defect study) were performed to demonstrate equivalent performance in bone. Macroscopic and microscopic evaluations demonstrate Kryptonite Bone Cement and control (predicate device) were stable and well tolerated in bone.

In summary, all testing performed indicates Kryptonite Bone Cement™ is substantially equivalent to predicate devices with regards to safety and performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Doctors Research Group, Inc.
c/o Mr. Justin Eggleton
Musculoskeketal Clinical Regulatory Advisors, LLC.
1331 H Street Northwest, 12th floor
Washington, DC 20005

NOV 16 2009

Re: K091382
Trade/Device Name: Kryptonite Bone Cement™
Regulation Number: 21CFR§ 882.5300
Regulation Name: Methyl methacrylate for cranioplasty
Regulatory Class: II
Product Code: GXP
Dated: September 24, 2009
Received: September 25, 2009

Dear Mr. Eggleton

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). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. 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.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings section of the device's labeling:

"The safety and effectiveness of this device have not been established for use in Vertebral Body Augmentation. The mechanical properties of this device have not been clinically evaluated and may not be adequate for load bearing applications."

Furthermore, the above warning must be prominently displayed in all labeling, including pouch, box, and carton labels, instructions for use, and other promotional materials, in close proximity to the trade name, of a similar point size, and in bold print.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification if the limitation statement described above is added to your labeling.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at 301-796-5770. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna-Bea Tillman, Ph.D., M.P.A.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K091382

Indications for Use

510(k) Number K091382

Device Name: Kryptonite Bone Cement™

Indications For Use: Kryptonite Bone Cement ™ is a resinous material for repairing cranial defects.

Prescription Use __√__ AND/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)

Mridula Nirmani

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K091382