K060763

SEP 22 2006

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS:
Stryker® Injectable Cement

General Information

Proprietary Name:	Stryker® Injectable Cement
Common Name:	Hydroxyapatite Cement
Proposed Regulatory Class:	Class II
Device Classification:	GXP (21 CFR 882.5300) Methyl methacrylate for cranioplasty
Submitter:	Stryker® 4100 East Milham Avenue Kalamazoo, MI 49001 877-534-2464 x 4226
Submitter's Registration #:	8010177
Manufacturer's Registration #:	9610726
Contact Person:	Wade T. Rutkoskie Manager, Regulatory Affairs and Quality Assurance Phone: 877-534-2464 x 4226 Fax: 269-323-4215
Summary Preparation Date:	January 4, 2006

Intended Use

Stryker® Injectable Cement is a self-setting, calcium phosphate cement intended for use in the repair of neurosurgical burr holes, contiguous craniotomy cuts and other cranial defects as well as in the augmentation or restoration of bony contour in the craniofacial skeleton.

Substantial Equivalency Information

Stryker® Injectable Cement is substantially equivalent to legally marketed K060061 Stryker® Injectable Cement and K043334 Stryker® HAC Rapid Set Cement.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 22 2006

Stryker
% Mr. Wade Rutkoskie
Manager RA/QA
750 Trade Centre Way, Suite 200
Portage, Michigan 49002

Re: K060763
Trade/Device Name: Stryker® Injectable Cement
Regulation Number: 21 CFR 882.5300
Regulation Name: Methyl methacrylate for cranioplasty
Regulatory Class: Class II
Product Code: GXP
Dated: August 22, 2006
Received: August 23, 2006

Dear Mr. Rutkoskie:

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

Sincerely yours,

Barbara Melkerson for

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(K) Number (if known): K

Device Name: *Stryker® Injectable Cement*

Indications for Use:

Stryker® Injectable Cement is a self-setting calcium phosphate cement indicated to fill bony voids or gaps of the skeletal system (i.e. extremities, ~~craniofacial~~, spine, and pelvis). These defects may be surgically created or osseous defects created from traumatic injury to the bone. The Stryker Injectable Cement is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure.

Stryker® Injectable Cement cured *in situ* provides an open void/gap filler that can augment provisional hardware (e.g., K-Wires, plates, screws) to help support bone fragments during the surgical procedure. The cured cement acts only as a temporary support media and is not intended to provide structural support during the healing process.

Stryker® Injectable Cement is a self-setting, calcium phosphate cement intended for use in the repair of neurosurgical burr holes, contiguous craniotomy cuts and other cranial defects as well as in the augmentation or restoration of bony contour in the craniofacial skeleton.

Prescription Use X AND/OR Over-the-Counter Use _____
(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)

Barbara Brehm

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

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(Posted November 13, 2003)