

DEC 30 2005

K051603

**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: MQV (21 CFR 888.3045) Filler, bone void, calcium compound  
FMF (21 CFR 880.5860) Syringe, Piston

Submitter: Stryker®  
4100 East Milham Avenue  
Kalamazoo, MI 49001  
877-534-2464 x 4062

Submitter's Registration #: 1811755

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: June 1, 2005

**Intended Use**

Option A: 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.

**Substantial Equivalency Information**

Stryker® Injectable Cement is substantially equivalent to legally marketed K043334 BoneSource® HAC Rapid Setting Cement, K041842 Norian SRS® Fast Set Putty, and K024336 Wright Medical MIIG II.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

DEC 30 2005

Mr. Wade T. Rutkoskie  
Manager, Regulatory Affairs & Quality Assurance  
Stryker®  
750 Trade Centre Way  
Suite 200  
Portage, MI 49002

Re: K051603

Trade/Device Name: Stryker® Injectable Cement  
Regulation Number: 21 CFR 888.3045  
Regulation Name: Resorbable calcium salt bone void filler device;  
Regulatory Class: II  
Product Code: MQV, FMF  
Dated: December 8, 2005  
Received: December 13, 2005

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.

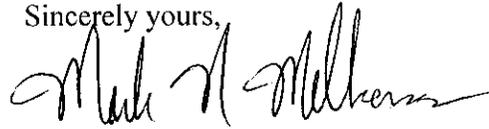
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson". The signature is fluid and cursive, written over the typed name below.

Mark N. Melkerson  
Acting 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 051603

Device Name: Stryker® Injectable Cement

Indications For Use:

Option A: 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.

Prescription Use X  
(21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(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 of \_\_\_\_\_  
Division of \_\_\_\_\_ Restorative  
and Neurological Devices

Page \_\_\_ of \_\_\_

510(k) Number: K051603

(Posted November 13, 2003)

K1