DEC 17 2007

K072118

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stryker®

Instruments

510(k) Summary

As required by section 21 CFR 807.92(c)

Device Sponsor: Stryker Instruments
4100 E. Milham Avenue
Kalamazoo, MI 49001
269-323-7700
Registration No.: 1811755

Device Name: Trade Name: Stryker Vertaplex Radiopaque Bone Cement
Common Name: PMMA Bone Cement
Classification Name: Polymethylmethacrylate (PMMA) bone cement
21 CFR§ 888.3027, LOD, NDN

Predicate Devices: Stryker Spineplex Radiopaque Bone Cement – K032945

Description: Vertaplex is Polymethyl Methacrylate cement used for the treatment of painful vertebral fractures based on the predicate device Spineplex. Vertaplex can be injected directly into the fractured vertebral body by either Vertebroplasty or Kyphoplasty procedures to relieve pain.

Intended Use: Vertaplex Radiopaque Bone Cement is indicated for the fixation of pathological fractures of the vertebral body using vertebroplasty of kyphoplasty procedures. Painful vertebral compression fractures may result from osteoporosis, benign lesions (hemangioma), and malignant lesions (metastatic cancers, myeloma).

Biocompatibility: All appropriate biocompatibility tests have been performed on Vertaplex and have met the standard requirements.

Substantial Equivalence (SE) Rational: Stryker Vertaplex PMMA Bone Cement is made of the same chemical components as Stryker Spineplex.

Performance Standards: Stryker Vertaplex has been developed in accordance with the FDA Guidance document entitled "Class II Special Controls Guidance Document: Polymethylmethacrylate (PMMA) Bone Cement."

Safety and Effectiveness: Stryker Vertaplex is substantially equivalent in design, materials, intended use and performance characteristics to the predicate device, Spineplex (K032945). In vitro testing shows that the device meets similar performance specifications as those for the predicate device. No new issues of safety or effectiveness are introduced by using this device.

Signed: _____
Jean W. Sheppard
Regulatory Analyst

Dated: 7-26-07

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Stryker Instruments
% Ms. Jean W. Sheppard
Regulatory Analyst
4100 E. Milham Avenue
Kalamazoo, MI 49001

DEC - 7 2007

Re: K072118
Trade/Device Name: Vertaplex Radiopaque Bone Cement
Regulation Number: 21 CFR 888.3027
Regulation Names: Polymethylmethacrylate (PMMA) bone cement
Regulatory Class: II
Product Code: NDN, LOD
Dated: November 28, 2007
Received: November 29, 2007

Dear Ms. Sheppard:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

Indications for Use

510(k) Number (if known): K072118

Device Name: Vertaplex Radiopaque Bone Cement

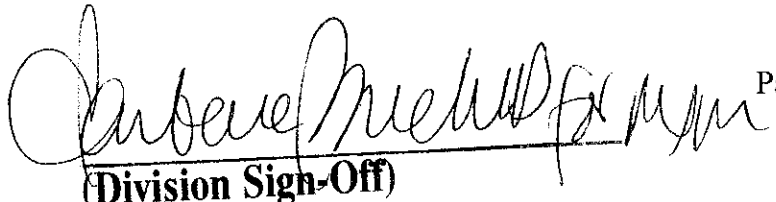
Indications for Use:

Vertaplex Radiopaque Bone Cement is indicated for the fixation of pathological fractures of the vertebral body using vertebroplasty of kyphoplasty procedures. Painful vertebral compression fractures may result from osteoporosis, benign lesions (hemangioma), and malignant lesions (metastatic cancers, myeloma).

Prescription Use ___X___ (Part 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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



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

510(k) Number K072118