K091606

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OCT 23 2009

stryker
Instruments

# 510(k) Summary

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| **510(k) Owner:** | Stryker Instruments<br>4100 E. Milham Avenue<br>Kalamazoo, MI 49001<br>(p) 269-323-7700<br>(f) 269-324-5412 |
| **Contact Person:** | Becky E. Ditty<br>Regulatory Affairs Analyst |
| **Registration No.:** | 1811755 |
| **Trade Name:** | Stryker Vertaplex HV |
| **Common Name:** | PMMA Bone Cement |
| **Classification Name:** | Polymethylmethacrylate (PMMA) Bone Cement |
| **Regulation Number:** | §888.3027 |
| **Predicate Device:** | Stryker Vertaplex Radiopaque Bone Cement (K072118) |
| **Device Description:** | Vertaplex HV is Polymethyl Methacrylate cement used for the treatment of painful vertebral fractures based on the predicate device Stryker Vertaplex PMMA Radiopaque Bone Cement (Vertaplex). Vertaplex HV can be injected directly into the fractured vertebral body by either Vertebroplasty or Kyphoplasty procedures to relieve pain. |
| **Indications for Use:** | Vertaplex HV Radiopaque Bone Cement is indicated for the fixation of pathological fractures of the vertebral body using vertebroplasty or kyphoplasty procedures. Painful vertebral compression fractures may result from osteoporosis, benign lesions (hemangioma), and malignant lesions (metastatic cancers, myeloma). |
| **Substantial Equivalence (SE) Rational:** | Stryker Vertaplex HV is composed of the same chemical components as Stryker Vertaplex PPMA Bone Cement and is equivalent in performance. |
| **Safety and Effectiveness:** | Stryker Vertaplex HV is substantially equivalent in design, materials, intended use and performance to the predicate device, Stryker Vertaplex PMMA Bone Cement (K072118). Testing shows that the device meets similar performance specifications as those for the predicate device. No new types of issues of safety or effectiveness are introduced by using this device. |
| **Submitted by:** | Becky E. Ditty<br>Regulatory Affairs Analyst<br>Signature |
| **Date Submitted:** | June 1, 2009 |

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

Stryker Instruments
% Ms. Becky E. Ditty
Regulatory Affairs Analyst
4100 E. Milham Avenue
Kalamazoo, MI 49001

OCT 23 2009

Re: K091606
Trade/Device Name: Vertaplex HV
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) bone cement
Regulatory Class: II
Product Code: NDN, LOD
Dated: October 6, 2009
Received: October 9, 2009

Dear Ms. Ditty:

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 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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

Enclosure

510(K) Number (if known): _____

Device Name: Vertaplex HV_____

**Indications for Use**

Vertaplex HV Radiopaque Bone Cement is indicated for the fixation of pathological fractures of the vertebral body using vertebroplasty or 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 IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

FOR M. MELKERSON

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K091606