DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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June 12, 2015

Stryker Corporation
Ms. Kristi Ashton
Staff Regulatory Affairs Specialist
4100 East Milham Avenue
Kalamazoo, Michigan 49001

Re: K150582
Trade/Device Name: VertaPlex® High Viscosity (HV) Radiopaque Bone Cement
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) bone cement
Regulatory Class: Class II
Product Code: NDN, LOD
Dated: May 15, 2015
Received: May 18, 2015

Dear Ms. Ashton:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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 Division of Industry and Consumer Education 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. 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 Industry and Consumer Education 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,

Lori A. Wiggins -S

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150582

Device Name Vertaplex® High Viscosity (HV) Radiopaque Bone Cement

Indications for Use *(Describe)*

VertaPlex HV Radiopaque Bone Cement is indicated for the fixation of pathological fractures of the vertebral body using vertebroplasty or kyphoplasty. It is also indicated for the fixation of pathological fractures of the sacral vertebral body or ala using sacral vertebroplasty or sacroplasty. Painful vertebral compression fractures may result from osteoporosis, benign lesions (hemangioma), and malignant lesions (metastatic cancers, myeloma).

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

I. Contact Details

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c. Contact Person:

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d. Date Submitted: June 11, 2015

II. Subject Device Name

Table 5-1-Subject Devices	
Name	Stryker® VertaPlex High Viscosity (HV) Radiopaque Bone Cement
Product code	NDN (primary) LOD (secondary)
Class	II
Regulation	21 CFR 888.3027 Polymethylmethacrylate (PMMA) bone cement
Part Names and Numbers	0406-622-000- VertaPlex HV™ (Dual Pack)
	0406-622-015- VertaPlex HV™ (Single Pack)

III. Legally Marketed Predicate Device (s)

Predicate Devices

Table 5-2- Predicate Device	
Name	Stryker® VertaPlex HV Radiopaque Bone Cement
510(k) Number	K091606
Product Code(s)	NDN (primary) LOD (secondary)
Regulation	21 CFR 888.3027 (Polymethylmethacrylate (PMMA) bone cement
Class	II
Part Names and Numbers	0406-622-000- VertaPlex HV™ (Dual Pack) 0406-622-015- VertaPlex HV™ (Single Pack)

Tables 5-1 and 5-2 identify and describe the predicate device that is currently in commercial distribution, and the subject device of this premarket notification.

IV. Device Description

VertaPlex® HV Radiopaque Bone Cement is comprised of a liquid component and powder component which when mixed together polymerize to form a hardened acrylic polymer. The mixture is in a pourable and injectable state for a period of time, before it cures to form a hardened structure, capable of long-term load support and bone augmentation in the treatment of symptomatic osteoporotic vertebral compression fractures.

The powder component of VertaPlex® HV Radiopaque Bone Cement is EO(Ethylene Oxide) sterilized and is packaged in a polyethylene/foil pouch while the liquid monomer is aseptically filled into an amber glass ampoule which is EO sterilized. The device contains the following components: Polymer powder (14g), Monomer liquid (9.5ml), and Barium Sulfate (6g

V. Indications for use

VertaPlex HV Radiopaque Bone Cement is indicated for the fixation of pathological fractures of the vertebral body using vertebroplasty or kyphoplasty. It is also indicated for the fixation of pathological fractures of the sacral vertebral body or ala using sacral vertebroplasty or sacroplasty. Painful vertebral compression fractures may result from osteoporosis, benign lesions (hemangioma), and malignant lesions (metastatic cancers, myeloma).

VI. Substantial Equivalence Comparison

Stryker® VertaPlex HV Radiopaque Bone Cement is substantially equivalent to the predicate Stryker® VertaPlex HV Radiopaque Bone Cement (K091606). Stryker® VertaPlex HV Radiopaque Bone Cement has an equivalent intended use, mechanism for use, and mode of action as compared to the predicate device. There have been no changes to the device's fundamental scientific technology or intended use, and yielded no increased risk to safety or effectiveness.

Feature	VertaPlex HV (Subject)	VertaPlex HV (Predicate) K091606	Explanation of Differences
Classification	Class II	Class II	Identical
Primary Product Code	NDN	NDN	Identical
Primary Regulation	888.3027 (Cement,Bone, Vertebroplasty)	888.3027 (Cement,Bone, Vertebroplasty)	Identical
Secondary Product Code	LOD	LOD	Identical
Regulation	888.3027 (Bone Cement)	888.3027 (Bone Cement)	Identical
Regulation description	Polymethylmethacrylate (PMMA) bone cement	Polymethylmethacrylate (PMMA) bone cement	Identical
Regulation Medical Specialty	Orthopedic	Orthopedic	Identical

Feature	**VertaPlex HV (Subject)**	**VertaPlex HV (Predicate) K091606**	**Explanation of Differences**
Indications for Use	VertaPlexHV Radiopaque Bone Cement is indicated for the fixation of pathological fractures of the vertebral body using vertebroplasty or kyphoplasty. It is also indicated for the fixation of pathological fractures of the sacral vertebral body or ala using sacral vertebroplasty or sacroplasty. Painful vertebral compression fractures may result from osteoporosis, benign lesions (hemangioma), and malignant lesions (metastatic cancers, myeloma).	VertaPlex HV Radiopaque Bone Cement both are 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).	Expanded indication to include vertebral body and sacrum and use in sacral vertebroplasty or sacroplasty.
Anatomical Sites	**Vertebral body and sacrum**	Vertebral body	**Addition of Indications for Use to include the vertebral body and sacrum**

VII. Non-Clinical

A cadaveric study in support of the expanded indication was completed. entitled: *A Study of Extravasation of Stryker® VertaPlex® HV Radiopaque Bone Cement Comparing the Meticulous Intraoperative Long Axis Versus Short Axis Techniques for Sacroplasty in Osteoporotic Cadavers.* This cadaveric study was conducted to provide data and guidelines as to the most conservative approach

for sacroplasty procedures, to mitigate the risk for extravasation in sacroplasty procedures.

No instances of cement extravasation after administration of VertaPlex HV Radiopaque Bone Cement were observed in the cadavers included in this study, using the long-axis technique or the short-axis technique. The results of this cadaveric study demonstrate no difference in the occurrence of cement extravasation after administration of VertaPlex HV Radiopaque Cement between the long- and short-axis techniques when the sacroplasty procedure is performed with meticulous imaging guidance by a physician who is trained and experienced in vertebral augmentation and acetabuloplasty and when careful post-procedural positioning is used.

Risk of extravasation specific to the new expanded anatomical area can be mitigated with the use of the guidance developed through completion of the cadaveric study which established surgical guidelines. These surgical guidelines, established by Stryker, are titled "*Surgical Procedure – Long and Short Axis Sacroplasty Techniques with Post-Procedure Positioning and CT Evaluation*."

VIII. Substantial Equivalence Conclusion

There have been no changes to the device since the previous clearance. Minor modifications to the packaging had no impact on the device's fundamental scientific technology or intended use, and yielded no increased risk to safety or effectiveness.

The additional Indications for Use to include the vertebral body and sacrum and sacroplasty procedures are supported by the clinical literature and the cadaveric study report. The cadaveric study yielded information to help mitigate the risk of extravasation with the use of the guidance established by Stryker titled "*Surgical Procedure – Long and Short Axis Sacroplasty Techniques with Post-Procedure Positioning and CT Evaluation*." In addition, the extensive literature review reveals the safety and efficacy of PMMA when used in the vertebral body and sacrum and in sacral vertebroplasty or sacroplasty procedures.

The information submitted herein supports the substantial equivalence of Stryker® Verteplex® HV Radiopaque Bone Cement for use in the vertebral body and sacrum and in sacral vertebroplasty or sacroplasty procedures.