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

March 31, 2020

Re: K192818
Trade/Device Name: Vertaplex HV High Viscosity Radiopaque Bone Cement, ES2® Augmentable Spinal System
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) bone cement
Regulatory Class: Class II
Product Code: PML, NKB, NDN
Dated: September 30, 2019
Received: October 1, 2019

Dear Kristi 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jesse Muir, PhD
Acting Assistant Director
DHT6C: Division of Restorative, Repair,
and Trauma Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192818

Device Name
Vertaplex® HV High Viscosity Radiopaque Bone Cement

Indications for Use *(Describe)*
VertaPlex® HV High Viscosity 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).

When used in conjunction with ES2® Augmentable Spinal System, Vertaplex® HV High Viscosity Radiopaque Bone Cement is intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the thoracic and lumbar spine in whom life expectancy is of insufficient duration to permit achievement of fusion. Vertaplex® HV High Viscosity Radiopaque Bone Cement and the ES2® Augmentable Spinal System are for use together at spinal levels where the structural integrity of the spine is not severely compromised.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
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Paperwork Reduction Act (PRA) Staff
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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192818

Device Name
ES2 ® Augmentable Spinal System

Indications for Use *(Describe)*
When used without cement, the ES2® Augmentable Spinal System is intended for posterior, non-cervical fixation as an adjunct to fusion for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, tumor and/or trauma (i.e., fracture or dislocation), spinal stenosis, curvatures (i.e., scoliosis, kyphosis, or lordosis), pseudarthrosis, and/or failed previous fusion.

When used in conjunction with the Vertaplex® HV High Viscosity Radiopaque Bone Cement, the ES2® Augmentable Spinal System is intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the thoracic and lumbar spine in whom life expectancy is of insufficient duration to permit achievement of fusion. ES2® Augmentable Spinal System augmented with the Vertaplex® HV High Viscosity Radiopaque Bone Cement is for use at spinal levels where the structural integrity of the spine is not severely compromised.

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)

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Traditional 510(k)

Stryker Instruments
4100 East Milham Ave, Kalamazoo, MI 49001 USA

510k Summary

1. Submitter

Stryker Instruments
4100 East Milham Avenue
Kalamazoo, MI 49001
Phone +1 (269) 323-7700
Fax +1 (269) 324-5412

FDA Establishment Registration Number: 1811755

Contact:

Kristi Ashton
Stryker Instruments
Regulatory Affairs
Sr. Staff Regulatory Affairs Specialist
Phone: +1 (269) 800-1692
Kristi.Ashton@Stryker.com

Date Submitted: March 26, 2020

2. Subject Devices

Trade Name: Vertaplex ® HV High Viscosity Radiopaque Bone Cement
Common Name: Polymethylmethacrylate (PMMA) Bone Cement
Product Codes: PML, NDN
Regulation: 21CFR888.3027

Trade Name: ES2® Augmentable Spinal System
Common Name: Thoracolumbosacral pedicle screw system
Product Codes: NKB
Regulation: 21CFR888.3070

3. Legally Marketed Predicate Device(s)

Predicate Device (Cement)			
Kyphon Xpede Bone Cement/Medtronic HV Bone Cement	K171938	NDN, PML	21CFR888.3027
Predicate Device (Screw Systems)			
CD Horizon Fenestrated Screw Set (Primary)	K171938	MNI	21CFR888.3070
ES2® Spinal System (Secondary)	K122845	NKB, KWP, MNH, MNI	21CFR888.3070

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4. Device Description

VertaPlex® HV High Viscosity Radiopaque Bone Cement is bone cement comprised of a liquid component and powder component which when mixed together polymerize to form a hardened acrylic polymer. The mixture is in an 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 High Viscosity Radiopaque Bone Cement is Ethylene Oxide (EO) 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, Monomer liquid and Barium Sulfate. Accessories to the subject cement device are compatible Stryker cement mixers such the Stryker Autoplex System and the Stryker PCD System.

ES2® Augmentable Spinal System is a gamma sterilized, titanium implantable screw with fenestrations and blocker designed as a stabilization solution for the aging spine. The subject system (screw and blocker) has been developed to provide improved anchorage of pedicle screws with and without Vertaplex® HV High Viscosity Radiopaque Bone Cement during pedicle screw augmentation in vertebrae with reduced bone quality as compared to pedicle screw augmentation in healthy bone.

5. Intended Use/Indications for use

VertaPlex® HV High Viscosity Radiopaque Bone Cement:

VertaPlex® HV High Viscosity 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).

When used in conjunction with ES2® Augmentable Spinal System, VertaPlex® HV High Viscosity Radiopaque Bone Cement is intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the thoracic and lumbar spine in whom life expectancy is of insufficient duration to permit achievement of fusion. VertaPlex® HV High Viscosity Radiopaque Bone Cement and the ES2® Augmentable Spinal System are for use together at spinal levels where the structural integrity of the spine is not severely compromised.

ES2® Augmentable Spinal System:

When used without cement, the ES2® Augmentable Spinal System is intended for posterior, non-cervical fixation as an adjunct to fusion for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of

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the disc confirmed by history and radiographic studies), spondylolisthesis, tumor and/or trauma (i.e., fracture or dislocation), spinal stenosis, curvatures (i.e., scoliosis, kyphosis, or lordosis), pseudarthrosis, and/or failed previous fusion.

When used in conjunction with the VertaPlex® HV High Viscosity Radiopaque Bone Cement, the ES2® Augmentable Spinal System is intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the thoracic and lumbar spine in whom life expectancy is of insufficient duration to permit achievement of fusion. ES2® Augmentable Spinal System augmented with the Vertaplex® HV Radiopaque Bone Cement is for use at spinal levels where the structural integrity of the spine is not severely compromised.

6. Comparison of Technological Characteristics with the Predicate Device

The Stryker Vertaplex® HV High Viscosity Radiopaque Bone Cement has not changed since it was cleared via K150582 and has the same intended use, principle of operation, and mode of action as the predicate devices. In addition, Vertaplex® HV High Viscosity Radiopaque Bone Cement and Kyphon Xpede Bone cement were previously determined to be substantially equivalent per K163032.

The Stryker ES2® Augmentable Spinal System has the same intended use as the predicate devices. The majority of the technical characteristics are similar/identical to the predicate devices K171938 CD Horizon Fenestrated Screw System and the secondary predicate K122845 ES2®Spinal System with a few exceptions such as added fenestrations and overall sterility. These differences have been found through testing, clinical literature, and a risk analysis to be insignificant and do not raise new questions of safety and effectiveness.

7. Non-Clinical

Bench

Static testing and interconnection strength testing were completed according to ASTM F1798-12 and Static pullout was performed per ASTM F1717-12. In addition, cadaver validation was performed. The subject devices were tested and met all respective acceptance criteria as specified per the individual test report. The testing was conducted in as similar a manner as possible to the clinical setting using the final finished form of the device. The acceptance criteria for the subject device were similar to the acceptance criteria for the Stryker predicate device. The performance testing further demonstrates equivalence because the subject device is shown to have equivalent functional characteristics as the predicate device.

Sterilization and Shelf Life

Vertaplex® HV Radiopaque Bone Cement will be sterilized per the same ETO methodology and dosage as was listed in submission K091606. The shelf life of 36 months for the subject cement has not been modified since submission K150582. The Vertaplex® HV Radiopaque Bone cement has been tested for bacterial endotoxins using

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Limulus amebocyte lysate (LAL) reagent and kinetic-turbidimetric methodology per ANSI/AAMI ST72:2011(R2016). The endotoxin limits for the Vertaplex® HV Radiopaque Bone Cement are <2.15 EU/device, as recommended for devices that have the potential to unintentionally extravasate out of the vertebral body, contact the cerebrospinal fluid or the circulatory system, resulting in exposure.

The ES2® Augmentable Spinal System is sterilized by gamma irradiation in accordance with AAMI guidelines and ISO 11137-2:2013 "Sterilization of health care products – Radiation – Part 2 to achieve sterility assurance level of 10^{-6}. Additionally, the ES2® Augmentable Spinal System has been tested for bacterial endotoxins using Limulus amebocyte lysate (LAL) reagent and kinetic-turbidimetric methodology per ANSI/AAMI ST72:2011(R2016). The endotoxin limits for the ES2® Augmentable Spinal System are <20 EU/device, as recommended for devices that are not intended to contact the cerebrospinal fluid.

ES2® Augmentable Spinal System has a shelf life of 5 years based on aging studies leveraged from the Stryker Spine Thoracolumbar (TL) Portfolio. This testing was completed for all packaging assemblies of TL System (Real Time and Accelerated Aging) in accordance with ASTM F1980 and ISO 11607.

Biocompatibility
The materials, processes and sterilization methodology for Vertaplex® HV Radiopaque Bone Cement are identical to that which was cleared in the original Vertaplex® HV submission K091606. Vertaplex® HV Radiopaque Bone Cement remains a biocompatible device.

The grade of material used by Stryker to manufacture the ES2® Augmentable Spinal System are ASTM F136 and ISO 5832 recommended. Since, the material has repetitively undergone traditional manufacturing processes and are documented as having a long history of use substantiated with supporting data from testing and literature citations, it was deemed unnecessary to conduct additional testing as allowed per FDA Guidance on ISO 10993. A biological risk assessment was completed and supported by information on the ES2® Augmentable Spinal System materials of construction, manufacturing processes/aids, gathered toxicological data on these materials, biological/chemical evaluation of equivalent devices, as well as other available literature. Based upon examination of this information, the risk assessment indicates that the risk of a toxic effect from the ES2® Augmentable Spinal System is negligible and that the devices can be considered safe for use as intended.

Traditional 510(k)

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8. Clinical

No clinical testing was deemed necessary for this 510(k).

A clinical literature review has been completed to support this pre-market notification. The clinical literature review provides evidence to support the safety and effectiveness of the use of PMMA bone cement with augmentable pedicle screws systems.

9. Substantial Equivalence Conclusion

Based upon the non-clinical testing completed and additional supporting documentation provided in this pre-market submission, the subject cement device and screw system have demonstrated safety and effectiveness. Based on the information provided, it can be concluded that the subject cement device, Vertaplex® HV High Viscosity Radiopaque Bone Cement, is substantially equivalent to the predicate cement devices, K171938 Kyphon Xpede Bone Cement/Medtronic HV Bone Cement; and the subject screw system, ES2® Augmentable Spinal System, is substantially equivalent to the predicate screw systems, K171938 CD Horizon Fenestrated Screw System and K122845 ES2® Spinal System.