Stryker Corporation
Ms. Becky Ditty
Principal Regulatory Affairs Specialist
4100 East Milham Avenue
Kalamazoo, Michigan 49001

Re: K162062
   Trade/Device Name: AVAmax Vertebral Balloon System, AVAflex Vertebral Balloon System
   Regulation Number: 21 CFR 888.1100
   Regulation Name: Arthroscope
   Regulatory Class: Class II
   Product Code: HRX, NDN
   Dated: September 30, 2016
   Received: October 3, 2016

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. 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 Parts 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,

Mark N. Melkerson -S

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

Enclosure
Indications for Use

Device Name
AVAmx Vertebral Balloon System

Indications for Use (Describe)
The AVAmx Vertebral Balloon System (system) is intended for the reduction of fractures and/or creation of a void in cancellous bone in the spine. This includes use during percutaneous vertebral augmentation. The system is to be used with cleared spinal Polymethylmethacrylate (PMMA) bone cements and Cortoss® Bone Augmentation Material indicated for use during percutaneous vertebral augmentation procedures, such as kyphoplasty.

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.

*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.*
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:

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PRASTaff@fda.hhs.gov

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Indications for Use

Device Name
AVAflex Vertebral Balloon System

Indications for Use (Describe)
The AVAflex Vertebral Balloon System (system) is intended for the reduction of fractures and/or creation of a void in cancellous bone in the spine. This includes use during percutaneous vertebral augmentation. The system is to be used with cleared spinal Polymethylmethacrylate (PMMA) bone cements indicated for use during percutaneous vertebral augmentation procedures, such as kyphoplasty.

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

- [x] Prescription Use (Part 21 CFR 801 Subpart D)
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

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510(k) Summary

Device Common Name: Inflatable Balloon Tamp (IBT) / Vertebral Balloon System
Device Proprietary Name: AVAmax Vertebral Balloon
AVAflex Vertebral Balloon

Applicant: Stryker Instruments
4100 E. Milham Ave
Kalamazoo, MI 49001

Contact: Becky Ditty
Principal Regulatory Affairs Specialist
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Kalamazoo, MI 49001
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Date Prepared: July 25, 2016

Classification Regulation: 21 CFR 888.1100, Class II, Arthroscope
21 CFR 888.3027, Class II, Polymethylmethacrylate (PMMA) bone cement

Panel: Orthopedics

Primary Product Code: HRX – Arthroscope
Secondary Product Code: NDN – Cement, Bone, Vertebroplasty

Predicate Devices: AVAmax Vertebral Balloon (K150523)
AVAflex Vertebral Balloon (K151125)

Indication for Use:
The AVAmax Vertebral Balloon System (system) is intended for the reduction of fractures and/or creation of a void in cancellous bone in the spine. This includes use during percutaneous vertebral augmentation. The system is to be used with cleared spinal Polymethylmethacrylate (PMMA) bone cements and Cortoss® Bone Augmentation Material indicated for use during percutaneous vertebral augmentation procedures, such as kyphoplasty.

The AVAflex Vertebral Balloon System (system) is intended for the reduction of fractures and/or creation of a void in cancellous bone in the spine. This includes use during percutaneous vertebral augmentation. The system is to be used with cleared spinal Polymethylmethacrylate (PMMA) bone cements indicated for use during percutaneous vertebral augmentation procedures, such as kyphoplasty.
Device Description:
The Stryker AVAmax and AVAflex Vertebral Balloon Systems are designed for use in percutaneous vertebral augmentation procedures. The balloon serves to create a cavity in the vertebral body, thereby reducing the fracture and preventing cement leakage, while still allowing for cement interdigitation. The balloon catheter is the functional part of the device that creates a cavity and reduces the fracture. The balloon catheter provides a conduit through which the physician can inflate the balloon at the distal end of the catheter.

Radiopaque markers provide for fluoroscopic visualization of the vertebral balloon prior to filling it with contrast media. The radiopaque balloon markers are located within the balloon.

The AVAflex includes a curved needle or a curved wire assembly. The introducer is a flexible radiopaque tube that retains its shape within the vertebral body when used in conjunction with the curved vertebral augmentation needle or wire assembly.

This 510(k) is being submitted for a labeling modification to the AVAmax and AVAflex devices as cleared in K150523 and K151125. Specifically, the purpose of this 510(k) is to modify the indications for use of the devices to include their use with all FDA cleared spinal Polymethylmethacrylate (PMMA) bone cements. Additionally, the AVAmax indication for use is being modified to include its use with Cortoss® Bone Augmentation Material, which was cleared in K080108.

The subject devices were both recently cleared in K150523 (AVAmax) and K151125 (AVAflex). Since those clearances there have been no changes to the device design that affect its performance. There have been no changes to the materials, manufacturing or processing of the subject devices their previous clearances in K150523 (AVAmax) and K151125 (AVAflex).

Sterilization and Shelf Life:
The AVAmax and AVAflex Vertebral Balloon Systems kits are provided sterile, for single use only, and are labeled with a shelf life of 2 years.

There have been no changes to the sterilization, packaging, or shelf life of the AVAmax and AVAflex Vertebral Balloon Systems since their previous clearances in K150523 and K151125. Therefore, no additional information is required to establish substantial equivalence.

Biocompatibility:
There have been no changes to the patient contacting materials, manufacturing or processing since the devices were previously cleared in K150523 and K151125. Therefore, no additional biocompatibility testing is required to establish substantial equivalence.

Performance Data:
As there were no changes to the device that effect its performance specifications, no new performance testing is required to establish substantial equivalence.

Substantial Equivalence Conclusion:
Based on the comparison of both the technological characteristics and the indications for use, the minor modifications made to the indication statements of the subject device do not alter the intended use and do not raise new questions of safety or effectiveness. Therefore, the subject devices can be found substantially equivalent to the predicate devices.