December 21, 2018

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

Re: K181752
Trade/Device Name: Stryker iVAS ® Elite Inflatable Vertebral Augmentation System (Stryker iVAS ® Elite Balloon Catheter)
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: Class II
Product Code: HRX, NDN
Dated: November 20, 2018
Received: November 21, 2018

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. 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Sarah B. Nelson -S

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

Enclosure
Indications for Use

The Stryker iVAS® Elite Inflatable Vertebral Augmentation System is intended to be used 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.

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510(k) Summary

1. Submitter

   a. 510(k) Owner: Stryker Instruments
      4100 E. Milham Avenue
      Kalamazoo, Michigan 49001
      USA
      Ph: +1-269-323-7700
      Fax: +1-269-324-5412

   b. FDA Establishment Registration Number: 1811755

   c. Contact Person: Kristi Ashton
      Ph: +1-269-389-5929
      Fax: +1-269-389-5412
      Kristi.Ashton@Stryker.com

   d. Date Submitted: December 14, 2018

2. Subject Device Name

   Trade Name: Stryker iVAS® Elite Balloon Catheter
   Common Name: Inflatable Bone Tamp
   Product Codes: HRX, NDN
   Regulation: 888.1100, 888.3027

3. Legally Marketed Predicate Devices

   Table 1 Predicate Device Table

<table>
<thead>
<tr>
<th>Predicate Devices</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Stryker iVAS ® Elite Balloon Catheter</td>
<td>K172116</td>
</tr>
<tr>
<td>Stryker iVAS® Elite Balloon Catheter</td>
<td></td>
</tr>
<tr>
<td>Stryker iVAS® Balloon Catheter</td>
<td>K123942</td>
</tr>
<tr>
<td>Stryker iVAS® Balloon Catheter</td>
<td></td>
</tr>
</tbody>
</table>

4. Device Description

   The Stryker iVAS ® Elite Balloon Catheter is a bone tamp with an inflatable component at the distal end. The balloon is inflated to create a void within the vertebral body. It is used with various accessories during vertebral augmentation.

   When the balloon is inflated with radiopaque fluid, the balloon expands axially and radially. Two radiopaque markers are fixed near the distal end of the balloon to show the
location of the balloon during placement. The balloon is coated with silicone to assist with insertion of the catheter into the access needle.

The patient contacting components of the device such as the balloon, catheter, catheter coating, lubricant and radiopaque material are externally communicating tissue/bone/dentin-limited contact ≤24 hrs.

Associated Accessories include:
- Access cannula/stylet
- Syringe
- Inflator
- Hand Drill
- Cement Tube

5. Principles of Operation / Mechanism of Action

The balloon catheter is the functional part of the device that creates a cavity and reduces the fracture. The balloon is designed to create a cavity by compressing cancellous bone and/or moving cortical bone as it inflates. After manufacturing, the balloon is covered with a protector called a sheath that the physician will remove prior to performing a procedure. 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.

After placing the access cannula into the fractured vertebral body, the physician places the access cannula and stylet in the desired location within the vertebral body, creating a channel for the balloon. The stylet is then removed, leaving the cannula in place. The deflated balloon is inserted through the access cannula. Contrast medium is injected into the balloon to inflate it. As the balloon inflates, it moves and compresses the cancellous bone, creating a void. The balloon is deflated and removed before cement injection takes place. Cement is then injected through the access cannula into this space.

6. Intended Use/Indications for use

The Stryker iVAS® Elite Inflatable Vertebral Augmentation System is intended to be used 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.
7. Comparison of Technological Characteristics with the Predicate Devices

The **subject and primary predicate** devices are **identical** in the following ways:

- Indications for use
- Design intent
- Classification
- FDA product codes and regulation
- Intended use
- Regulation medical specialty
- Placed percutaneously under fluoroscopy
- Uses syringe for inflation
- Balloon diameter
- Balloon wall thickness
- Sheath material
- Radiopaque balloon markers
- Radiopaque balloon material
- Sliding pin material
- Catheter material
- Balloon material
- Balloon lubricant
- Depth markers
- Color of shaft
- Color of distal tip
- Color of hub
- Sterilization method
- SAL
- Single use
- Maximum inflation pressure

The **subject and primary predicate** devices **differ** in the following ways:

- Sheath color
- Tamp size
- Maximum recommended inflation volume

The **subject and secondary predicate** devices are **identical** in the following ways:

- Tamp size
- Maximum recommended inflation volume

8. Non-Clinical

8.1 Biocompatibility

Biocompatibility testing, adopted per K172116, was performed following the recommendations of ISO 10993-1 and FDA Guidance (Use of International Standard ISO- 10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing" June 2016) as appropriate for limited exposure (≤24 hours) externally communicating, tissue/bone/dentin devices. All biocompatibility testing met the requirements of the respective test method, thus supporting the biocompatibility of the subject device iVAS ® Elite Balloon Catheter.
The biocompatibility testing confirms that the subject device is non-sensitizing, non-irritating and non-toxic (cytotoxic and systemic). The biocompatibility testing met all acceptance criteria deeming this to be a biocompatible medical device.

8.2 Bench

A Risk Management File (RMF), in compliance with EN ISO 14971:2012, Medical Devices-Application of risk management to medical devices, was completed to assess the impact of the subject device modification. In accordance with the risk assessment, verification and validation testing was performed in accordance with EN ISO 14971:2012 in an effort to mitigate risk where possible.

All bench testing pertaining to the subject device modifications met their respective acceptance criteria as specified per the individual test report. Each test report was performed using industry accepted standards. The testing was conducted using the final finished device in a manner as similar as possible to how the balloon will be used by the healthcare professional. The performance testing demonstrates equivalence because the subject device is shown to have the same functional characteristics as the predicate device. Per the risk management assessment, the subject device does not introduce any new types of safety and effectiveness questions.

The acceptance criteria for the subject device are similar to the acceptance criteria for the predicate devices, demonstrating equivalence of the subject device to the predicate balloon catheter devices.

Catheter Flexibility Testing and Cold Age testing have been adopted from K093429. Accelerated Age testing has been adopted from K172116. Real-time testing is currently underway for the subject device.

Cadaveric testing was completed to provide evidence that the use of the subject balloon with a high inflation pressure of 808psi would not cause any new concerns regarding safety and effectiveness. This cadaveric testing was completed by a physician using the subject device in a manner as similar as possible to how the balloon would be used in the clinical setting. The subject balloon was inflated under fluoroscopic guidance. Following the inflation of the balloon, the physician evaluated nearby anatomical structures for adverse events related to the high-pressure balloon inflations. There were no adverse events following the inflations with the subject balloon catheter. This testing confirms that the modifications to the subject device do not raise new questions of safety and effectiveness.
### Table 2 Design Controls

#### Sheath Colorant change

<table>
<thead>
<tr>
<th>Modification</th>
<th>Test Performed</th>
<th>Acceptance Criteria</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sheath colorant change</td>
<td>Biocompatibility (sheath)</td>
<td>Adoption (K172116)</td>
<td>Pass</td>
</tr>
</tbody>
</table>

#### Balloon Catheter Length and Volume Change

- Balloon tamp size changes since the predicate 510(k) submission K172116:
  - Balloon tamp length is shorter than the predicate
  - Balloon tamp is longer than the predicate
  - Maximum recommended inflation volume larger than predicate
  - Maximum recommended inflation volume smaller than predicate

<table>
<thead>
<tr>
<th>Modification</th>
<th>Test Performed</th>
<th>Acceptance Criteria</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Constrained Burst</td>
<td>Constrained Burst was performed to simulate the user inflating the balloon beyond the maximum rating stated in the Instructions for Use. The subject device met all acceptance criteria.</td>
<td>Pass</td>
<td></td>
</tr>
<tr>
<td>Un-Constrained Burst, Length to Diameter and One-way Valve Torque</td>
<td>Unconstrained Burst was performed to verify that the balloon meets a minimum open air inflation volume. The subject device met all acceptance criteria.</td>
<td>Pass</td>
<td></td>
</tr>
<tr>
<td>Insert, Retract, Sheath Removal, Assembly Strength, Tensile Force</td>
<td>Insertion and Retraction Force was performed to show the force required to insert and remove the catheter into the access needle. The subject device met all acceptance criteria.</td>
<td>Pass</td>
<td></td>
</tr>
<tr>
<td>Sheath shipping test</td>
<td>Balloon Sheath must remain on balloon after bulk shipping configuration</td>
<td>Pass</td>
<td></td>
</tr>
<tr>
<td>Cadaveric testing</td>
<td>No damage to adjacent anatomical structures following high pressure balloon inflation</td>
<td>Pass</td>
<td></td>
</tr>
</tbody>
</table>

#### Packaging

<table>
<thead>
<tr>
<th>Modification</th>
<th>Test Performed</th>
<th>Acceptance Criteria</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Same as listed above</td>
<td>Real-time packaging testing</td>
<td>Device must meet all acceptance criteria while determining expiration date using either accelerated or real-time aging methods.</td>
<td>Pass</td>
</tr>
</tbody>
</table>
9. Clinical Testing
No clinical testing was deemed necessary for this 510(k).

10. Substantial Equivalence Conclusion
The subject and the predicate devices have the same intended use, fundamental scientific technology, principle of operation, and mode of action. Although there are slight differences in the technological characteristics between the subject and predicate devices, these differences have been found to be insignificant overall.

All bench testing of the subject device met its respective acceptance criteria as specified per the individual test report. Each test report was performed using industry accepted standards as listed in Section 12 Standard Summary Reports. The testing was conducted using the final finished device in a manner as similar as possible to how the subject device will be used by the healthcare professional. The acceptance criteria for the subject device is similar to the acceptance criteria for the predicate device. Showing that the subject device meets the acceptance criteria at the same identified risk level (low risk) demonstrates equivalence to the predicate devices. The performance testing further demonstrates equivalence because the subject device is shown to have the same functional characteristics as the predicate devices.

The modifications to the subject Stryker iVAS® Elite Balloon Catheter do not raise new types of safety and effectiveness questions. Therefore, the subject Stryker iVAS® Elite Balloon Catheter is substantially equivalent to the predicate device, the Stryker iVAS® Elite Balloon Catheter (K172116) and secondary predicate Stryker iVAS® Balloon Catheter (K123942)