

K093419

4100 E. Milham Avenue
Kalamazoo, MI 49001
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MAR 18 2010



Instruments

510(k) Summary

510(k) Owner: Stryker Instruments
4100 E. Milham Avenue
Kalamazoo, MI 49001
(p) 269-323-7700
(f) 269-324-5412

Contact Person: Becky Ditty

Registration No.: 1811755

Trade Name: Stryker® iVAS Balloon Catheter

Common Name: Inflatable Bone Tamp

Classification Name: Arthroscope
Cement, Bone, Vertebroplasty

Regulation Number: §888.1100
§888.3027

Product Code: HRX
NDN

Predicate Device: Kyphx Xpander Inflatable Bone Tamps (K041454)

Device Description: The Stryker® iVAS balloon catheter is a bone tamp with an inflatable component (balloon) at the distal end. The balloon is inflated to create a void within the vertebral body.

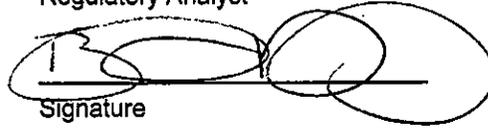
Indications for Use: The Stryker® iVAS Inflatable Vertebral Augmentation System (system) is intended to be used for the reduction of fractures and/or creation of a void in cancellous bone in the spine. This includes use during percutaneous vertebral augmentation. The system is to be used with cleared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

Substantial Equivalence (SE) Rational: The Stryker® iVAS balloon catheter is equivalent in intended use, technological characteristics, safety, and effectiveness to the Kyphx Xpander Inflatable Bone Tamp.

Safety and Effectiveness: The Stryker® iVAS balloon catheter does not raise any new safety and efficacy concerns when compared to a similar device already legally marketed. Therefore, the Stryker® iVAS balloon catheter is equivalent to the existing device.

Submitted by:

Becky E. Ditty
Regulatory Analyst



Signature

Date Submitted:

3.17.2010



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Stryker Instruments
% Ms. Becky Ditty
4100 East Milham Avenue
Kalamazoo, Michigan 49001

MAR 18 2010

Re: K093419

Trade/Device Name: Stryker iVAS Inflatable Vertebral Augmentation System
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) bone cement
Regulatory Class: II
Product Code: NDN, HRX
Dated: March 11, 2010
Received: March 12, 2010

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.

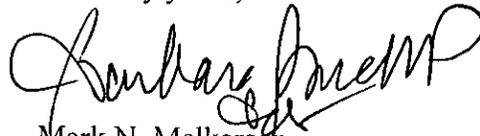
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR 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.

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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): _K093419_____

Device Name: Stryker iVAS Inflatable Vertebral Augmentation System_____

Indications for Use

The Stryker® iVAS Inflatable Vertebral Augmentation System (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 indicated for use during percutaneous vertebral augmentation procedures, such as kyphoplasty.

Prescription Use X

and/or

Over-The-Counter Use

(Part 21 CFR 801 Subpart D)

(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

 FOR M. MELKERSON

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

510(k) Number K093419