DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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September 4, 2014

Stryker Instruments
Ms. Brittney M. Larsen
Senior Regulatory Affairs Representative
4100 E. Milham Avenue
Kalamazoo, Michigan 49001

Re: K141673
Trade/Device Name: Stryker iVAS 8 Gauge Bone Biopsy Kit
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-urology biopsy instrument
Regulatory Class: Class II
Product Code: KNW
Dated: July 7, 2014
Received: August 8, 2014

Dear Ms. Larsen:

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,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical 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)*
K141673

Device Name
Stryker® iVAS® 8 Gauge Bone Biopsy Kit

Indications for Use *(Describe)*

The Stryker iVAS Bone Biopsy Kit can be used as a biopsy tool to remove a sample of bone tissue from a vertebral body for diagnostic purposes using a coring, cutting or aspiration technique.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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.

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K141673

510(k) Summary

I. Contact Details

a. 510(k) Owner: Stryker Instruments
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USA
Ph: +1-269-323-7700
Fax: +1-269-324-5412

b. FDA Establishment Registration Number: 1811755

c. Contact Person: Brittney M. Larsen
Ph: +1-269-389-5293
Fax: +1-269-389-5412
Brittney.Larsen@Stryker.com

d. Date Submitted: June 20, 2014

II. Device Name

a. Trade Name: Stryker® iVAS® 8 Gauge Bone Biopsy Kit

b. Common Name: Vertebral Bone Biopsy Needles

c. Classification Name: *Gastroenterology-urology biopsy instrument* (21 CFR 876.1075, Product code KNW)

d. Classification: II

III. Legally Marketed Predicate Device(s)

510(k) Number	Product Code	Trade Name	Manufacturer
K032943	KNW	Stryker Bone and Vertebral Body Biopsy Kit	Stryker Instruments

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I. Purpose of the Special 510(k) Submission

Stryker submits this **Special 510(k): Device Modification** to request clearance for a modification to our Stryker Bone and Vertebral Body Biopsy Kit(s). The predicate device(s) are currently cleared for 10-13gauge (G) sizes. The subject modification is to add an 8-G size product offering, which is outside the currently cleared size range. This device modification does not change the intended use, indications for use or the fundamental scientific technology of the predicate device(s).

II. Device Description

The Stryker® Inflatable Vertebral Augmentation System (iVAS®) 8 Gauge Bone Biopsy Kit may be used as a biopsy tool to remove a sample of bone tissue from a vertebral body for diagnostic purposes using a coring, cutting or aspiration technique.

The Stryker® iVAS® 8 gauge bone biopsy kit is a disposable device, intended for single-use, individually packaged and provided sterile. The biopsy device will be sold in a kit consisting of a coaxial biopsy needle, obturator and syringe. The biopsy kit is used with access cannula and stylet accessories of compatible size. The access cannula and stylet are sold separately and are Class I exempt under 21 CFR 888.4200, product code OAR (*Injector, vertebroplasty (does not contain cement)*.

III. Indications for use

The Stryker iVAS Bone Biopsy Kit can be used as a biopsy tool to remove a sample of bone tissue from a vertebral body for diagnostic purposes using a coring, cutting or aspiration technique.

IV. Substantial Equivalence Comparison

The Stryker® iVAS® 8 Gauge Bone Biopsy Kit is substantially equivalent to the Stryker Bone and Vertebral Body Biopsy Kit predicate device(s) (K032943). Stryker claims this equivalence because the Stryker® iVAS® 8 Gauge Bone Biopsy Kit has an equivalent intended use, mechanism for use, and mode of action as compared to the predicate device(s). The differences between the Stryker® iVAS® 8 Gauge Bone Biopsy Kit and the predicate device(s) have been identified and explained in **Table 2**, the substantial equivalence comparison matrix.

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Table 2. Substantial equivalence comparison matrix

Description	Stryker Bone and Vertebral Body Biopsy Kit(s) (Predicate)	Stryker® iVAS® 8 Gauge Bone Biopsy Kit (Subject)	Explanation of Differences
General Information			
Classification	Class II	Class II	Identical
Regulation	21 CFR 876.1075, *Gastroenterology-urology biopsy instrument*	21 CFR 876.1075, *Gastroenterology-urology biopsy instrument*	Identical
Product code	KNW, *Instrument, Biopsy*	KNW, *Instrument, Biopsy*	Identical
Review panel	78 Gastroenterology/Urology	78 Gastroenterology/Urology	Identical
Indications for use	Stryker's Bone and Vertebral Body Biopsy Kits can be used as a biopsy tool to remove a sample of bone tissue from a vertebral body for diagnostic purposes using a coring, cutting or aspiration technique.	The Stryker iVAS Bone Biopsy Kit can be used as a biopsy tool to remove a sample of bone tissue from a vertebral body for diagnostic purposes using a coring, cutting or aspiration technique.	Identical
Use	Single-use	Single-use	Identical
Anatomical sites	Bone and vertebral body	Bone and vertebral body	Identical
Visualization technique	Fluoroscopy	Fluoroscopy	Identical
Method of placement	Percutaneous	Percutaneous	Identical
Mechanics of action	Manual	Manual	Identical
Mode of action	Suction	Suction	Identical
Shelf life	2 years	1 year	Similar – the intent is to extend the shelf life for the subject device upon successful completion of aging studies.

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Table 2 continued. Substantial equivalence comparison matrix

Description	Stryker Bone and Vertebral Body Biopsy Kit(s) (Predicate)	Stryker® iVAS® 8 Gauge Bone Biopsy Kit (Subject)	Difference
Size Information			
Penetration depth	5 - 7.5-in.	5 - 7.5-in.	Identical
Biopsy needle and Obturator	Compatible with 10, 11 and 13-gauge access cannulae/stylets	Compatible with 8-gauge access cannula/stylet	The subject device biopsy needle diameter increased to accommodate user preference for an 8-gauge biopsy system. Verification and validation testing have been conducted to ensure there are no new concerns of safety and effectiveness.
Patient Contacting Material Information			
Biopsy needle	Stainless steel	Stainless steel	Identical
Performance Information			
Tensile force (Pull test)	Withstand < 15-lbs. of force	Withstand < 15-lbs. of force	Identical
Biopsy needle tip	Swaged	Not swaged	Subject biopsy needle does not exhibit a swaged, tapered, distal tip in order to increase sample size. Verification and validation testing have been conducted to ensure there are no new concerns of safety and effectiveness.
Sterilization Information			
Sterilization method	Gamma irradiation, VDmax25	Gamma irradiation, VDmax25	Identical
Sterilization assurance level (SAL)	10^{-6}	10^{-6}	Identical
Minimum sterilization dose	25-kilograys (kGy)	25-kilograys (kGy)	Identical

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V. Non-clinical Testing

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 an effort to mitigate risk where possible. Testing performed includes: functional, packaging integrity and sterilization testing. See **Table 3**, for a summary of the non-clinical testing and acceptance criteria used to evaluate the subject device modification. Stryker has determined that the device modification to the predicate device(s) raises no new questions of safety or effectiveness.

Table 3. Non-clinical testing and acceptance criteria summary

Non-Clinical Testing	Acceptance Criteria
Impact testing	Biopsy needle to withstand impact loads of at least 25 cycles at 2-in-lb.
Tensile force testing	Biopsy needle and obturator to withstand a force measuring less than 15-lbs.
Non-axial torque testing	Biopsy needle handle to withstand a force measuring less than 25-in-lb.
Axial torque testing	Biopsy needle handle to withstand a force measuring less than 3.25-in-lb.
Functional testing	Non-swaged biopsy needle must retain an equivalent or greater average subjective size measurement than the swaged biopsy needle.
Sterilization testing	Sterilization method is VDmax25, in compliance with the ISO 11137-1 and ISO11137-2 standards, acceptance criteria includes: • Bioburden less than 1000 CFU • Less than 2 positive tests of sterility in product verification dose experiment • SAL 10^{-6}

VI. Clinical Testing

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

VII. Conclusion / Substantial Equivalence (SE) Rationale

The Stryker® iVAS® 8 Gauge Bone Biopsy Kit is substantially equivalent in intended use, indications for use, technological characteristics, safety and effectiveness to the previously cleared Stryker Bone and Vertebral Body Biopsy

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Conclusion/Substantial Equivalence (SE) Rationale continued.

Kit. The predicate device(s) have the same fundamental scientific technology, basic design, functional characteristics and applications. The device modification does not introduce any new concerns of safety or effectiveness. Therefore, the Stryker® iVAS® 8 Gauge Bone Biopsy Kit is substantially equivalent to the existing predicate device(s).