October 5, 2017

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

Re: K172558
Trade/Device Name: Stryker iVAS Bone Biopsy Kit .
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-Urology Biopsy Instrument
Regulatory Class: Class II
Product Code: KNW
Dated: August 23, 2017
Received: August 24, 2017

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. 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 (DICE) 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" (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 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 (DICE) 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,

Jennifer R. Stevenson -S3

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)*
K172558

Device Name Stryker iVAS® Bone Biopsy Kit

Indications for Use *(Describe)* The Stryker iVAS® Bone Biopsy Kit can be used as a biopsy tool to remove sample tissue from bone or vertebral body using a coring, cutting or aspiration technique.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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K172558
510(k) Summary

1. Submitter

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d. Date Submitted: October 2, 2017

2. Subject Device Name

Trade Name: Stryker iVAS® Bone Biopsy Kit
Common Name: Instrument, Biopsy
Product Codes: KNW

Regulation: 21CFR876.1075

3. Legally Marketed Predicate Device

Predicate Device: Coaxial Bone and Vertebral Body Biopsy Needle (K070091)
Reference Device: Stryker iVAS® 8G Bone Biopsy Kit (K141673)

4. Device Description

The Stryker iVAS® Bone Biopsy Kit can be used as a biopsy tool to remove sample tissue from bone or vertebral body using a coring, cutting or aspiration technique. The subject device is disposable, intended for single use, and is provided sterile to the end user. The mechanism of action for obtaining a biopsy is manual and the principle of operation is through suction. The biopsy device will be sold in a kit configuration consisting of a coaxial biopsy needle, obturator and syringe. The subject biopsy kit is used with an access cannula and stylet of compatible size. The access cannula and stylet are sold separately and are Class I exempt per 21 CFR 888.4200, product code OAR (injector, vertebroplasty (does not contain cement).

5. Intended Use/Indications for use

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

6. Comparison of Technological Characteristics with the Predicate Device

Table 5-1 Comparison of Technological Characteristics

Description	Stryker iVAS® Biopsy Kit (Subject)	Coaxial Bone and Vertebral Body Biopsy Needle (K070091) (Predicate)
Classification	Class II	Class II
Product code	KNW, Instrument, Biopsy	KNW, Instrument, Biopsy

Description	Stryker iVAS® Biopsy Kit (Subject)	Coaxial Bone and Vertebral Body Biopsy Needle (K070091) (Predicate)
Indications for use	The Stryker iVAS® Bone Biopsy Kit can be used as a biopsy tool to remove sample tissue from bone or vertebral body using a coring, cutting or aspiration technique.	This device is intended for use by a physician performing a bone or vertebral body biopsy using a coring, cutting, or aspiration technique.
Intended use/target population	Used in patients in need of a bone or vertebral body tissue diagnostics	Used in patients in need of a bone or vertebral body tissue diagnostics
Gauge Configurations	8G,10G,11G	10G, 11G, 13G
Biopsy needle Dimensions	The differences in the dimensions are nominal across the gauge sizes.	The differences in the dimensions are nominal across the gauge sizes.
Biopsy Needle-Material	Stainless steel	Stainless steel
Biopsy Needle Handle Material	Plastic	Plastic
Biopsy needle sheath (safety feature)	Plastic	Plastic
Penetration depth	There are nominal differences in the penetration depth of the subject and predicate devices.	There are nominal differences in the penetration depth of the subject and predicate devices.
Jaw size	There are nominal differences in the jaw size of the subject and predicate devices.	There are nominal differences in the jaw size of the subject and predicate devices.
Brush Size (diameter and depth)	N/A	N/A
Obturator Material	Stainless steel	Stainless steel

Description	Stryker iVAS® Biopsy Kit (Subject)	Coaxial Bone and Vertebral Body Biopsy Needle (K070091) (Predicate)
Obturator Handle Material	Plastic	Stainless Steel
Sterilization method	Gamma Irradiation, VDmax25	Ethylene Oxide (Eo)
Sterilization assurance level	10-6	10-6

8. Non-Clinical

Biocompatibility:

The materials of construction for the Stryker iVAS ® Bone Biopsy Kit have not changed since the device was originally cleared via K032943 (10G, 11G) and K141673 (8G). Therefore, biocompatibility testing is not required.

Bench:

The following bench testing was conducted on the subject Stryker iVAS® Bone Biopsy Kit. The testing was conducted in a manner as similar as possible to how the biopsy device will be used by the healthcare professional.

Axial Torque and Non-axial Torque (11G) was performed to verify torsional performance of the subject device. All samples surpassed all acceptance criteria.

Compressive force testing was completed on the obturator (10G) to simulate compression during clinical use. All samples surpassed all acceptance criteria.

Axial Tensile Force (10G) was performed to verify the functional performance of the subject device at T=0. All samples surpassed all acceptance criteria.

Compressive Force and Axial Tensile Force was performed on the obturator (11G) to verify functional and compressive performance. All samples surpassed all acceptance criteria.

Impact and Axial Compressive testing was to verify the impact and compressive performance of the subject device. All samples surpassed all acceptance criteria.

Impact testing was performed on the subject device to confirm functional specifications. All samples surpassed all acceptance criteria.

The acceptance criteria for the predicate devices is similar to the acceptance criteria for the subject bone biopsy kit, demonstrating equivalence of the subject device to the predicate biopsy devices.

9. Clinical Testing

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

10. Substantial Equivalence Conclusion

The Stryker iVAS ® Bone Biopsy Kit and predicate devices have the same fundamental scientific technology, principal of operation and mode of action.

The addition of bone to the intended use for the subject device does not raise new questions of safety and effectiveness. A review of recalls, Maude data, clinical literature, and a risk review was completed. There are no new or previously unidentified complications or additional harms associated with the use of biopsy needles when the indication is expanded to include bone.

Although there are a few differences in the technological characteristics of the subject and predicate devices, they are insignificant overall. The technological differences between the subject and predicate devices do not raise new types of safety and effectiveness questions. The performance testing completed proves that the subject device has the same performance characteristics as the predicate device.

Therefore it is proposed that the subject Stryker iVAS® Biopsy Kit is substantially equivalent to the predicate device (Coaxial Bone and Vertebral Body Biopsy Needle (K070091).