February 26, 2018

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

Re: K180327
Trade/Device Name: Stryker iVAS® 13G Bone Biopsy Kit
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-Urology Biopsy Instrument
Regulatory Class: Class II
Product Code: KNW
Dated: February 5, 2018
Received: February 6, 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. 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 and Part 809) ; 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.

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.

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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180327

Device Name

Stryker iVAS ® 13G Bone Biopsy Kit

Indications for Use *(Describe)*

The Stryker iVAS® 13G 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)*

☒ 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.

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K180327
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 BSN, RN
Staff Regulatory Affairs Specialist
Regulatory Affairs
Instruments Division
Stryker Corporation
Ph: +1-269-389-5929
Fax: +1-269-389-5412
Kristi.Ashton@Stryker.com

d. Date Submitted: February 23, 2018

2. Subject Device Name

Trade Name: Stryker iVAS ®13G Bone Biopsy Kit
Common Name: Instrument, Biopsy
Product Codes: KNW
Classification: Class II
Regulation: 21CFR876.1075

3. Legally Marketed Predicate Device

Table 7-1-Predicate Device

Predicate Device	510(k)	Product Code	Manufacturer
Stryker iVAS® Bone Biopsy Kit (11G)	K172558	KNW	Stryker Instruments

K172558 represents the most recent clearance for the predicate device.

Table 7-2 Reference Device

Reference Device	510(k)	Product Code	Manufacturer
Coaxial Bone and Vertebral Body Biopsy Needle (K070091)	K070091	KNW	Stryker Instruments

K070091 represents the most recent clearance for the reference device.

4. Device Description

The Stryker iVAS ®13G 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.

5. Principles of Operation/Mechanism of Action

The mechanism of action for obtaining a biopsy is manual and the principle of operation is through suction.

6. Intended Use/Indications for use

Stryker iVAS ®13G 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.

7. Comparison of Technological Characteristics with the Predicate Device

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

- FDA product codes and regulation
- Intended use
- Indications for use
- Single-use, multiple samples per patient
- Placed percutaneously under fluoroscopy
- Manual suction
- Shelf life
- Material (needle & obturator)-(patient contacting)
- Material (sheath)-(non-patient contacting)
- Needle tip design
- # of teeth
- Penetration depth
- Needle/obturator length
- Sterilization method
- SAL
- Minimum sterilization dose
- Packaging configuration

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

- Gauge size- The subject device is a 13G biopsy kit and the predicate device is an 11G biopsy kit. The 13G needle size is smaller than the 11G but this difference will not affect the performance of the subject device as demonstrated through testing. The

previously cleared Stryker 13G Coaxial Bone and Vertebral Body Biopsy Needle (K070091) is being used in this submission as a reference device due to its identical gauge size.

- Needle dimension- The subject device's needle dimensions are nominally smaller than the predicate device. The change in the outer dimension does not change the performance of the device and does not raise new types of safety and effectiveness questions.
- Diameter (obturator)-The subject obturator is nominally smaller than the predicate device. With the modification for a smaller size, the function and performance of the obturator remains the same. The obturator does not contact the patient. The smaller size does not raise new types of safety and effectiveness questions.
- Handle colorant (needle)-The subject needle handle utilizes the same handle material as the predicate device. The difference in the subject and predicate needle handles relates to the colorants used. The colorant in the subject handle is a dark grey and the colorant in the predicate device handle is green. The handle color of the subject needle enables the end user to distinguish between different gauge sizes. The handle does not touch the patient and does not raise new types of safety and effectiveness questions.
- Handle colorant (obturator)-The subject and predicate obturator handles have the same handle material. The difference in the subject and predicate obturator handles relates to the colorants used. The subject obturator handle is a dark grey and the predicate obturator handle is green. The handle color of the subject obturator enables the end user to distinguish between different gauge sizes. The handle does not touch the patient and does not raise new types of safety and effectiveness questions.

8. Non-Clinical

Biocompatibility:

A biocompatibility evaluation was completed on the Stryker iVAS Access Cannula, which has identical materials of construction and manufacturing process as the subject device. All testing completed met the requirements of the respective test methods as per the recommendations of ISO 10993-1 and FDA Guidance (Use of International Standard ISO-10993-1, "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.

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 testing pertaining to the subject device modifications met their respective acceptance criteria as specified per the individual test report. Per the risk management assessment, the subject device does not introduce any new types of safety and effectiveness questions.

The following bench testing was conducted on the subject Stryker iVAS® Bone Biopsy Kit.

Table 7-2 Design Controls

Modification	Test Performed	Acceptance Criteria	Result
Material Information			
Biopsy Handle Colorant changed from green to dark grey	The biopsy needle handle does not touch the patient and is thereby out of scope of ISO 10993.		N/A
Obturator Handle Colorant changed from green to dark grey	The obturator does not touch the patient and is thereby out of scope of ISO 10993.		N/A
Size Information			
Modification	Test Performed		
Decreased biopsy needle outer diameter and inner diameter (jaw size) to accommodate user preference for a 13G Bone Biopsy Kit	Axial Torque on the needle	Axial torque testing was completed to test how the subject device withstands twisting. All samples surpassed all acceptance criteria.	
	Non-axial Torque on the needle	Non-axial torque testing was completed to test how the subject device withstands bending. All samples surpassed all acceptance criteria.	
	Impact and Compressive Force on the needle	Impact and compressive force was completed to simulate impact and compression of the subject device while it is being advanced into bone. All samples surpassed all acceptance criteria.	
	Tensile Force on needle	Tensile force testing was completed to verify the force required to pull the needle off of the handle is higher than the force needed to remove the device from bone. All samples surpassed all acceptance criteria.	
Decreased obturator diameter to accommodate user preference for a 13G Bone Biopsy Kit	Compressive Force on the obturator	Compressive force was completed to simulate compression of the subject device when removing the sample from the needle. All samples surpassed all acceptance criteria.	

The device modification, assessed by the risk management file and validated with testing deemed necessary, does not introduce any new concerns regarding the safety and effectiveness of the subject device.

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

10. Substantial Equivalence Conclusion
The Stryker iVAS ® Bone Biopsy Kit and the predicate device have the same intended use, fundamental scientific technology, principle of operation, and mode of action.

Although there are slight differences in the technological characteristics of the subject and predicate devices, these differences were found to be insignificant overall. In accordance with the Risk Management File (RMF), verification and validation testing demonstrates that the subject device has the same performance characteristics as the predicate device.

The modifications to the subject Stryker iVAS® Biopsy Kit do not raise new types of safety and effectiveness questions. Therefore it is proposed that the subject Stryker iVAS® Biopsy Kit is substantially equivalent to the predicate device, the Stryker iVAS® Bone Biopsy Kit (11G-K172558).