Stryker Instruments
Kelebogile Moumakwa
Staff Regulatory Affairs Specialist
1941 Stryker Way
Portage, Michigan 49002

April 29, 2024

Re: K240526
Trade/Device Name: POWERream Xia/Serrato
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw System
Regulatory Class: Class II
Product Code: NKB, HWE
Dated: February 23, 2024
Received: February 23, 2024

Dear Kelebogile Moumakwa:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Eileen Cadel -S Digitally signed by Eileen Cadel -S Date: 2024.04.29 09:44:20 -04'00' for

Colin O'Neill, M.B.E.
Assistant Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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)*
K240526

Device Name
POWEReam Xia/Serrato

Indications for Use *(Describe)*
The intended use is to facilitate the placement of the pedicle screws using the power technique (cordless). When the attachment is attached, the Stryker Power Tools provide power to rotate the screwdrivers for the insertion of pedicle screws.

Pedicle screws from select Stryker Spine implant systems may be implemented in the non-cervical spine using powered instrumentation.

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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510(k) Summary

stryker

Submitter Information

This Premarket Notification is submitted by:

Stryker Instruments
1941 Stryker Way
Portage
MI 49002
USA

Contact Information

Kelebogile Moumakwa
Staff Regulatory Affairs Specialist
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Date Prepared: February 2024

Device Name

Table 1: Subject Device Information

Subject Device Information	
Trade/ Proprietary Name	POWEReam Xia/Serrato
Regulation Names	Thoracolumbosacral pedicle screw system Instrument, Surgical, Orthopedic, Ac-Powered Motor And Accessory/Attachment
Regulation Numbers	21 CFR 888.3070 21 CFR 878.4820
Review Panel	Orthopedic
Product Codes	NKB, HWE
Regulatory Class	Class II

Predicate Device

The legally marketed predicate for the subject device is detailed in Table 2.

Table 2: Predicate Device Information

Primary Predicate Device Name	510(k)	Product Code	Manufacturer
POWEReam ¼" Drive	K233300	NKB/HWE	Stryker Instruments

Indications for Use

The intended use is to facilitate the placement of the pedicle screws using the power technique (cordless). When the attachment is attached, the Stryker Power Tools provide power to rotate the screwdrivers for the insertion of pedicle screws.

Pedicle screws from select Stryker Spine implant systems may be implemented in the non-cervical spine using powered instrumentation.

Device Description

The Stryker POWEReam Xia/Serrato is an attachment used with a Stryker battery powered handpiece that drives accessories to achieve their intended function. The design reduces the speed and increases the torque output from the handpiece by a ratio of 5:1.

The purpose of this premarket notification is to seek clearance for the Stryker POWEReam Xia/Serrato (part number 4405-240-000).

Comparison of Regulatory Information

Description	Subject	Predicate	Comparison Assessment
	Stryker POWERream Xia/Serrato	Stryker POWERream ¼" Drive (K233300)	
Type of Use	Prescription Use Only	Prescription Use Only	**Identical**
Classification of Device	Class II	Class II	**Identical**
Primary Product Code	NKB, HWE	NKB, HWE	**Identical**
Primary Regulation	21 CFR 888.3070	21 CFR 888.3070	**Identical**
Regulation Name	Thoracolumbosacral Pedicle Screw System	Thoracolumbosacral Pedicle Screw System	**Identical**
Review Panel	Orthopedic	Orthopedic	**Identical**
Indications for Use	The intended use is to facilitate the placement of the pedicle screws using the power technique (cordless). When the attachment is attached, the Stryker Power Tools provide power to rotate the screwdrivers for the insertion of pedicle screws. Pedicle screws from select Stryker Spine implant systems may be implemented in the non-cervical spine using powered instrumentation.	The intended use is for drilling, reaming, and decorticating of bone and other bone-related tissue during general surgical orthopedic procedures in a variety of surgical procedures. It is also usable in the placement of screws, wires, pins, and other fixation devices. This attachment is designed for general surgical use where hard tissue and/or bone must be cut, reamed,	**Identical** The first two paragraphs of the predicate device contain the orthopedic indications. These indications are not in scope of this submission. The intended use related to placement of pedicle screws is equivalent.

Description	Subject	Predicate	Comparison Assessment
	Stryker POWEReam Xia/Serrato	Stryker POWEReam ¼" Drive (K233300)	
		drilled, and/or fixated with screws, including but not limited to, the hand, wrist, elbow, sternum, shoulder, foot, ankle, knee, and hip. The intended use is also to facilitate the placement of the pedicle screws using the power technique (cordless). When the attachment is attached, the Stryker Power Tools provide power to rotate the screwdrivers for the insertion of pedicle screws, in non-cervical spine surgical procedures.	
Patient Population	General	General	**Identical**
Contraindications	None Known	None Known	**Identical**
Conditions for Use	Professional use only in a professional healthcare environment.	Professional use only in a professional healthcare environment.	**Identical**

Comparison of Technological Characteristics

The subject device has the same intended use as the predicate device as they are both used to facilitate placement of pedicle screws in non-cervical spine procedures. The subject device is indicated to facilitate the placement of pedicle screws using the Stryker Spine Xia and Serrato screwdrivers, while the predicate device is indicated to facilitate the placement of pedicle screws using tools with a 1/4" square fitting.

The design of both the subject and predicate device are similar. Both transmit torque and speed provided from the powered handpiece to associated accessories and both reduce the speed and increase the torque output from the handpiece at a 5:1 gear ratio reduction. The accessory connection end is similar with quick connection design technology; however, the geometries are different as they are designed to connect to different accessories.

Risk evaluation and performance testing have shown that the differences do not introduce new questions of safety and effectiveness and that the subject is at least as safe and effective as the predicate, supporting a determination of substantial equivalence. The evaluation and testing have demonstrated that the subject device is substantially equivalent to the predicate device.

Summary of Non-Clinical Testing

A suite of non-clinical testing was executed to demonstrate substantial equivalence to the predicate device. Testing included:

- Performance Design Verification Testing
- Human Factors and Usability Engineering
- Simulated Use Design Validation Testing

All pre-defined acceptance criteria for the above tests have been met. Results from this testing confirm that the subject device performs as intended and supports a determination of substantial equivalence to the predicate device.

Summary of Clinical Testing

Clinical testing was not required for this Traditional 510(k).

Conclusion

The Stryker POWERream Xia/Serrato is substantially equivalent to the predicate device currently cleared under K233300 as it has the same intended use, same design, principle of operation and technological characteristics. No new questions of safety or effectiveness have been raised as compared to the predicate. Performance testing has demonstrated that the Stryker POWERream Xia/Serrato is substantially equivalent to the predicate device.