



Stryker Instruments
Marie Gildea
Senior Staff Regulatory Affairs Specialist
1941 Stryker Way
Portage, Michigan 49002

December 26, 2023

Re: K233300

Trade/Device Name: POWEReam 1/4" Drive
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw System
Regulatory Class: Class II
Product Code: NKB, HWE
Dated: December 7, 2023
Received: December 7, 2023

Dear Marie Gildea:

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: 2023.12.26
09:00:55 -05'00'

for

Colin O'Neill, MBE
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

Indications for Use

Submission Number (if known)

K233300

Device Name

POWERream 1/4" Drive

Indications for Use (Describe)

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, 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.

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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7.1 Submitter Information

This Premarket Notification is submitted by:

Stryker Instruments
1941 Stryker Way
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MI 49002
USA

Contact Information

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Date Prepared: December 2023

7.2 Device Name

Table 7.1: Subject Device Information

Subject Device Information	
Trade/ Proprietary Name	POWEReam ¼” Drive
Regulation Name	Thoracolumbosacral pedicle screw system
Review Panel	Orthopedic
Product Code	NKB
Regulatory Class	Class II

7.3 Predicate Device

The legally marketed predicate for the subject device is detailed in Table 7.2.

Table 7.2: Predicate Device Information

Predicate Device Name	510(k)	Product Code	Manufacturer
Stryker Xia 3 Power Adaptor	K200666	NKB	Stryker Spine

7.4 Indications for Use

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, 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 the non-cervical spine using powered instrumentation.

7.5 Device Description

The Stryker POWEReam 1/4" Drive 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 accessories are intended for drilling, reaming, and decorticating of bone and other bone-related tissue during general orthopedic procedures in a variety of surgical procedures.

The purpose of this premarket notification is to seek clearance for a new indication for the Stryker POWEReam 1/4" Drive (part number 4405-250-000). This indication is for facilitating the placement of pedicle screws in non-cervical spine surgical procedures.

7.6 Comparison of Technological Characteristics

The subject device has the same intended use as the predicate device. Both are attachments used with a Stryker battery-powered handpiece that drives accessories to achieve their intended function using the power technique. Specifically, both are used to facilitate the placement of pedicle screws in non-cervical spine procedures.

The design of both the subject and predicate device are also similar. Both transmit torque and speed provided from the handpiece to associated accessories and both connect to handpieces and provide the torque to accessories under power. A difference in the design between the subject and predicate is that the predicate device attaches to a Hudson Modified Trinkle attachment that reduces the speed and increases the torque output from the handpiece at either a 3:1 or 5:1 gear ratio reduction. The subject device reduces the speed itself (from the Powered handpiece) and increases the torque output from the handpiece at a 5:1 gear ratio reduction. There are also differences in dimensions (Diameter, Speed and Mass) between the two devices.

Risk evaluation and performance testing have shown that the differences between the predicate and subject device do not introduce new issues of safety and effectiveness. The evaluation and testing have demonstrated that the subject device is substantially equivalent to the predicate device.

7.7 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.

7.8 Summary of Clinical Testing

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

7.9 Conclusion

The Stryker POWEReam ¼” Drive is substantially equivalent to the predicate device currently cleared under K200666 as it has the same intended use, similar design, principle of operation and technological characteristics. The addition of the indication for the facilitating of the placement of pedicle screws in the non-cervical does not raise new questions of safety or effectiveness. Performance testing has demonstrated that the Stryker POWEReam ¼” Drive is substantially equivalent to the predicate device.