October 5, 2021

Stryker GmbH
Keith Neligan
Senior Staff Regulatory Affairs Specialist
325 Corporate Drive
Mahwah, New Jersey 07430

Re: K211508
Trade/Device Name: Steinmann Pins and Kirschner Wires
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HTY, JDW
Dated: August 18, 2021
Received: August 24, 2021

Dear Keith Neligan:

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; 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 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,

Brent L. Showalter, Ph.D.
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)*
K211508

Device Name
Steinmann Pins

Indications for Use *(Describe)*
The Steinmann Pins are intended to be used in conjunction with a compatible Stryker external supporting frame for stabilization of open and/or unstable fractures and where soft tissue injury may preclude the use of other fracture treatments such as IM rodding, casting and other means of internal fixation.

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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The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
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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)*
K211508

Device Name
Kirschner Wires

Indications for Use *(Describe)*
The Kirschner Wires are intended for use in skeletal traction for alignment and reduction of long bone fractures, and as guide wires in hip pinning, and as fracture fixation devices in certain other small bone fractures.
• For use as guide wires in hip pinning procedures,
• For use in aligning and reducing long bone fractures,
• For use in securing temporary stabilization of bone fractures such as olecranon fractures; patella fractures; tibia plateau fractures; hand and foot bone fractures; humeral, radial and ulnar fractures.
• For use with cerclage wire/cable in treating greater trochanter fractures.

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)

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510(k) Summary

Proprietary Names:	Steinmann Pins Kirschner Wires
Common Name:	Pin, Fixation, Threaded; Pin, Fixation, Smooth
Regulation Description:	Smooth or threaded metallic bone fixation fastener
Regulation Number:	21 CFR 888.3040
Classification Product Code:	JDW, HTY
Device Class:	II
Submitter:	Stryker GMBH Bohnackerweg 1 2545 Selzach, Switzerland
Contact Person:	Keith Neligan Senior Staff Regulatory Affairs Specialist IDA Business & Technology Park, Carrigtwohill, Co. Cork, Ireland T45 HX08 Phone: +00 353 87 7995645
Date:	August 09, 2021
Primary Predicate Device	Apex Fixation Pins (K001886)
Additional Predicate Device	Osteo Kirschner Wires (K971962)
Device Description:	The Steinmann Pins and Kirschner Wires are designed for multiple purposes which allow the use in skeletal traction for alignment and reduction of bone fractures, function as fracture fixation devices in certain fractures, preliminary fixation for implants (for example plates) and for evaluation of screw trajectories or guidance for cannulated instruments. The Steinmann Pins and Kirschner Wires are available in different dimensions and provide several design features. The dimensions vary in diameter and length. The design features are the tip geometry which can be a three-sided trocar tip or a two-sided diamond tip on either one end or both ends of the pin. Additionally, some pins are threaded. The pins and wires are made from stainless steel (1.4441).
Indications for Use:	The Steinmann Pins are intended to be used in conjunction with a compatible Stryker external supporting frame for immobilization of open and/or unstable fractures and where soft tissue injury may preclude the use of other fracture treatments such as IM rodding, casting and other means of internal fixation.

The Kirschner Wires are intended for use in skeletal traction for alignment and reduction of long bone fractures, and as guide wires in hip pinning, and as fracture fixation devices in certain other small bone fractures.
• For use as guide wires in hip pinning procedures,
• For use in aligning and reducing long bone fractures,
• For use in securing temporary stabilization of bone fractures such as olecranon fractures; patella fractures; tibia plateau fractures; small hand and foot bone fractures; humeral, radial and ulnar fractures.
• For use with cerclage wire/cable in treating greater trochanter fractures.

Summary of Technologies:

Steinmann Pins:
The intended use of the subject devices (Steinmann Pins) are similar to those detailed in the predicate device (Apex Fixation Pins). There is no change in the fundamental scientific technology shared by both the subject device and predicate device.

Kirschner Wires
The intended use of the subject devices (Kirschner Wires) are similar to those detailed in the predicate device (Osteo Kirschner Wires). There is no change in the fundamental scientific technology shared by both the subject device and predicate device.

Performance Data (Nonclinical):

Non-Clinical Performance and Conclusions:
The Steinmann Pins and Kirschner wires are single use instruments, sterilized by means of radiation; they are sterile stainless steel wires with diameter and lengths comparable to those of the predicate devices. The design is substantially equivalent to that of the predicate devices; the indications for use are included in those of the predicate devices; the material of the Steinmann Pins and Kirschner wire are the same as that of the predicate device. Moreover, Steinmann Pins and Kirschner wires conform to the international standard ISO 5838-1. Testing, therefore, is not needed to demonstrate that the subject devices are substantially equivalent to other legally marketed Steinmann Pins and Kirschner wires.

Packaging tests were performed according ISO 11607-1 and ISO 11607-2. All bench tests performed in accordance with ASTM standards.

Clinical Performance and Conclusions:
Clinical data and conclusions were not needed for these devices to demonstrate substantial equivalence to the predicate devices.

Conclusion:

The subject devices have the same intended use and similar indications for use as the predicate devices. The subject devices use the same operating principle, incorporate the same basic design and labeling and are manufactured and sterilized using the same materials and processes as the predicate devices.
The performance data and analyses demonstrate that:
• any differences do not raise new questions of safety and effectiveness as established with performance testing; and
• the subject devices are at least as safe and effective as the legally marketed predicate devices