March 25, 2024

Stryker GmbH
Ileana Freige
Staff Specialist Regulatory Affairs
Bohnackerweg 1
Selzach, 2545
Switzerland

Re: K233919
Trade/Device Name: VariAx 2 Distal Radius System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: HRS, HWC
Dated: December 13, 2023
Received: December 13, 2023

Dear Ileana Freige:

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,

Tejen D. Soni -S

For
Shumaya Ali, M.P.H.
Assistant Director
DHT6C: Division of Restorative, Repair
and Trauma 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K233919

Device Name

VariAx 2 Distal Radius System

Indications for Use *(Describe)*

The VariAx 2 Distal Radius System is indicated for the fixation of fractures, osteotomies, nonunions and malunions of the bones of the hand and wrist, including osteopenic bone.

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

Proprietary name:	VariAx 2 Distal Radius System
Common name:	Plate, Fixation, Bone and Screw, Fixation, Bone
Primary Product Code:	HRS
Regulation Number:	21 CFR 888.3030: Single/multiple component metallic bone fixation appliances and accessories
Associated Product Code:	HWC
Regulation Number:	21 CFR 888.3040: Smooth or threaded metallic bone fixation fastener
Device Class:	Class II
Sponsor:	Stryker GmbH Bohnackerweg 1 2545 Selzach, Switzerland
Contact Person:	Ileana Freige Staff Specialist, Regulatory Affairs Dr. Homer Stryker Strasse 1 2545 Selzach, Switzerland Phone: +41 79 757 61 27 ileana.freige@stryker.com
Date Prepared:	December 13, 2023
Predicate Device:	VariAx 2 Distal Radius System (K212581)
Reference Device:	VariAx Distal Radius Plating System (K133974)
Device Description:	This Traditional 510(k) submission is being supplied to the U.S. FDA to gain clearance to market the new devices of the VariAx 2 Distal Radius System. This line extension consists of anatomically pre-contoured plates for the treatment of simple and complex fractures of the distal radius, together with specialized instrumentation. All new plates are manufactured from CP Ti Grade 2 (Type II anodization) and are available in different sizes and left/right versions. The plates will be provided both non-sterile and sterile-packaged. They will use the well-established SmartLock technology to allow variable angle screw locking. The plates can be used with non-locking and locking VariAx 2 T8 screws. The VariAx 2 T8 screws have been previously cleared under K191412.

Indications for Use:

The VariAx 2 Distal Radius System is indicated for the fixation of fractures, osteotomies, nonunions and malunions of the bones of the hand and wrist, including osteopenic bone.

Comparison to predicate device:

The intended use and indications of the subject devices are identical as those of the predicate devices. There is no change in the fundamental scientific technology shared by both the subject and predicate devices.

Performance Data:

Non-Clinical Performance:
The new VariAx 2 Distal Radius plates are single use devices, available in sterile and non-sterile presentations. Sterile plates are sterilized by means of radiation.
Comparative assessment to the predicate and reference systems demonstrated substantial equivalence. The following factors were considered:

- Engineering assessment of cross-section analysis in the fatigue area
- Plate/Screw interface: Static cantilever bending
- Plate/Screw interface: Dynamic cantilever bending
- Plate/Screw interface: Torque to failure
- MR assessment of magnetically induced displacement force per ASTM F2052, magnetically induced torque per ASTM F2213, RF-induced heating per ASTM F2182, and image artifacts per ASTM F2119.
- Packaging tests were performed according to ISO 11607-1 and ISO 11607-2.
- Biocompatibility evaluation according to ISO 10993-1

Clinical Performance:
Clinical data was not needed for the subject devices to demonstrate substantial equivalence to the predicate devices.

Conclusion:

The subject devices have identical intended use and 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 same materials and processes as the predicate devices.
The performance analyses demonstrate that:

- Any differences do not raise new questions of safety and effectiveness; and
- The subject devices are at least as safe and effective as the legally marketed predicate devices.