January 19, 2022

Stryker GmbH
Keith Neligan
Senior Staff Regulatory Affairs Specialist
Contact Address325 Corporate Drive
Mahwah, New Jersey 07430

Re: K212581
Trade/Device Name: VariAx 2 Distal Radius System, VariAx 2 Distal Ulna 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
Dated: August 11, 2021
Received: August 16, 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,

Shumaya Ali, MPH
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K212581

Device Name
VariAx 2 Distal Radius

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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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:

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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)*
K212581

Device Name
VariAx 2 Distal Ulna

Indications for Use *(Describe)*
The VariAx 2 Distal Ulna System is indicated for the fixation of fractures, osteotomies, nonunions, and malunions of the 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.

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K212581 - 510(k) Summary

Proprietary Name:	VariAx 2 Distal Radius & VariAx 2 Distal Ulna
Common Name:	Plate, Fixation, Bone
Regulation Description:	Single/multiple component metallic bone fixation appliances and accessories.
Regulation Number:	21 CFR 888.3030
Classification Product Code:	HRS
Device Class:	II
Sponsor:	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 Fax: +
Date:	JAN 19, 2022
Predicate Device:	Primary Predicate: VariAx Distal Radius Plating System Line Extension (K133974) Additional Predicate Devices: VariAx 2 Mini Fragment & VariAx 2 System (K191412), TriMed Wrist Fixation System (K060041), LCP Distal Ulna Plate (K063049)
Device Description:	The distal radius plates consist of an anatomically shaped Dorsal DR Plate for the double column DR fractures. The anatomically shaped Dorsal Lateral DR, Dorsal Medial DR, Lateral DR and Volar Rim DR plates are used for fragment specific plating of the distal radius. Lateral DR plate for the radial styloid fractures, a Dorsal Medial DR Plate and a Dorsal Lateral DR Plate for the medially or laterally displaced dorsal DR fractures, and a Volar Rim DR Plate for the volar rim DR fractures. The Lateral DR plate, Dorsal Medial DR and Dorsal Lateral DR plates will provide screw/peg fixation of the distal DR fragments as an optional to fixation with K-wires. The Wrist Spanning plate is intended for temporary internal fixation of the comminuted distal radius fractures and wrist and serves as an alternative to an External Fixator. Additionally, it can be applied for complementary stabilization in combination with the other fracture fixation plates. The VariAx 2 Distal Ulna (DU) plates consist of the DU Base Plate and the DU Hook Plate. The DU hook plate is used for fixation of ulnar styloid fractures and the DU base plate is used for fractures of the distal ulnar head and/or shaft.

All new VariAx 2 implants will use the well-established SmartLock technology to allow variable angle screw locking. The plates will be available non-sterile in VariAx 2 Wrist Tray, and also sterile-packaged. The plates can be used with non-locking and locking VariAx 2 T8 screws. The VariAx 2 T8 screws have received 510(k) clearance (K180500).

All plates (except the Wrist Spanning plate) are made from CP Ti Grade 2 (anodized Type II). The Wrist Spanning plate is made from Ti Alloy (Ti6Al4V ELI).

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.

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

Comparison to Predicate Device:

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

Performance Data (Nonclinical):

Non-Clinical Performance and Conclusions:
The VariAx 2 Distal Radius and VariAx 2 Distal Ulna plates are single use devices, available in sterile and non-sterile forms. Sterile plate are sterilized by means of radiation.

Comparative assessment and mechanical testing to the predicate systems demonstrated substantial equivalence. The following factors were considered:

- Dynamic component/construct test (4-point bending according to ASTM F382 and DQI 30-021)
- Dynamic cantilever bending
- Static cantilever bending
- Torque to failure
- Push out force

The aforementioned testing demonstrated that the VariAx 2 Distal Radius and VariAx 2 Distal Ulna systems are substantially equivalent to the predicate devices. Additionally, MR assessments 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 demonstrate that the VariAx 2 Distal Radius and VariAx 2 Distal Ulna systems are MR conditional.

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 similar 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