July 8, 2022

Stryker GmbH
Jonathan Schell
Sr. Staff Regulatory Affairs Specialist
325 Corporate Drive
Mahwah, New Jersey 07430

Re: K221346
Trade/Device Name: Stryker VariAx 2 MIS Calcaneus
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: May 6, 2022
Received: May 9, 2022

Dear Jonathan Schell:

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, 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221346

Device Name
VariAx 2 MIS Calcaneus

Indications for Use *(Describe)*
Stryker VariAx 2 MIS Calcaneus is indicated for fractures of the calcaneus.

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 MIS Calcaneus
Common Name:	Single/multiple component metallic bone fixation appliances and accessories (21 CFR 888.3030)
Regulation Description:	Single/multiple component metallic bone fixation appliances and accessories (21 CFR 888.3030)
Regulation Number:	21 CFR 888.3030
Product Code:	HRS
Device Class:	Class II
Sponsor:	Stryker GmbH Bohnackerweg 1 2545 Selzach / Switzerland
Contact Person:	Jonathan Schell, RAC Sr. Staff Regulatory Affairs Specialist 325 Corporate Drive Mahwah, NJ 07430 Phone: 484-889-5804 Fax: 201-831-6500
Date Prepared:	May 6, 2022
Predicate:	K063875: Stryker Foot Plating System
Additional Predicate:	K132898: Zimmer Biomet A.L.P.S. Calcaneal Plating System

Description

This Traditional 510(k) submission is submitted to the U.S. FDA to provide authorization to market the VariAx 2 MIS Calcaneus plates. The goal of the Subject Device VariAx 2 MIS Calcaneus is to offer a comprehensive range of calcaneal implants and instruments in one system utilizing the VariAx 2 platform technology and SOMA database for the design of the plates.

The Subject Device VariAx 2 MIS Calcaneus has an equivalent Intended Use and Indications for Use as the Predicate Device and shares the same principle of operation.

Intended Use

Stryker VariAx 2 MIS Calcaneus is a non-active implant(s) intended to provide temporary stabilization for bones or bone fragments.

Indications for Use

Stryker VariAx 2 MIS Calcaneus is indicated for fractures of the calcaneus.

Summary of Technologies

A comparison of the Subject Device VariAx 2 MIS Calcaneus shows that the Subject Device is substantially equivalent to the Predicate Device regarding Intended Use, material, design, and operational principle.

Non-Clinical Testing

- The Subject Device(s) biocompatibility profile is equivalent to the previously cleared Reference Device(s) regarding material formulation, processing, sterilization, and geometry.
- The Subject Device sterilization methods and parameters remain the same as the Predicate Device.
- Verification testing (ASTM F382-17) was performed on the Subject Device and the acceptance criterion was fulfilled.
- MR compatibility testing was conducted on the Subject Device.

Clinical Testing

Clinical testing was not required for this submission.

Conclusion

The Subject Device VariAx 2 MIS Calcaneus has an equivalent Intended Use and Indications for Use as the Predicate Device, and equivalent technological characteristics to the Predicate Device. Therefore, the information provided in this submission demonstrates substantial equivalence of the Subject Device to the Predicate Device.