Stryker GmbH
Jemin Dedania
Associate Manager Regulatory Affairs
325 Corporate Drive
Mahwah, New Jersey 07430

November 22, 2019

Re: K192675
Trade/Device Name: VariAx Foot
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: September 24, 2019
Received: September 26, 2019

Dear Jemin Dedania:

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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K192675

Device Name
VariAx Foot

Indications for Use *(Describe)*

The VariAx Foot system is intended for use in internal fixation, reconstruction or arthrodesis of small bones including the fore, mid- and hind foot and ankle. Examples of these procedures include but are not limited to:

- Replantation
- Lag screw techniques
- Joint fusions
- Corrective osteotomies
- Treatment of 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)

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 Foot
Common Name:	Screw, Fixation, Bone Plate, Fixation, Bone
Regulation Description:	Smooth or threaded metallic bone fixation fastener Single/Multiple component metallic bone fixation appliances and accessories
Regulation Number:	21 CFR 888.3030, 21 CFR 888.3040
Product Code:	HWC (Screw, Fixation, Bone/Washer) HRS (Plate Fixation, Bone)
Device Class:	Class II
Sponsor:	Stryker GMBH Bohnackerweg 1 2545 Selzach / Switzerland
Contact Person:	Jemin Dedania Associate Manager Regulatory Affairs 325 Corporate Drive Mahwah, NJ 07430 Phone: (201)-831-6461 Fax: (201) – 831-6500
Additional Contact Person:	Christine Adib Regulatory Affairs Intern
Date Prepared:	08/26/2019
Primary Predicate:	Stryker Foot Plating System (K063875)
Reference Predicate Device:	VariAx Elbow System (K101056)

Description

VariAx Foot is a system used for internal fixation applications. VariAx Foot consists of self-tapping locking and non-locking screws, as well as corresponding washers and compatible bone plates. Since its original submission (K063875), the screws of the system have been modified. The modification includes the addition of a cutting flute to the 2.7mm and 3.5mm locking and non-locking screws and a change in the Torx head of the 2.7mm screws. The lengths of the 2.7mm

diameter screws range from 8-50mm. The lengths of the 3.5mm diameter screws range from 10-70mm.

Indications for Use

VariAx Foot is intended for use in internal fixation, reconstruction or anthrodesis of small bones including the fore, mid- and hind foot and ankle. Examples of these procedures may include but are not limited to:

- Replantation
- lag screw techniques
- joint fusions
- corrective osteotomies
- treatment of fractures.

Summary of Technologies

A comparison of the systems demonstrated that the subject VariAx Foot is substantially equivalent to the Stryker Foot Plating System (K063875) in regard to intended use, material, design, and operational principles.

Non-Clinical Testing

An engineering rational has been provided to demonstrate equivalence of the subject device to the predicate with respect to insertion torque and pull out force.

LAL testing was performed to establish that the subject devices meet the less than 20 EU/device limit.

Clinical Testing

Clinical Testing was not required for this submission.

Conclusion

The subject VariAx Foot system described in this submission has the same indications, intended use, target patient population, technological characteristics, and materials as the predicate devices. The subject VariAx Foot system is substantially equivalent to the predicate Stryker Foot Plating System (K063875).