DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

May 8, 2017

Stryker GmbH
Mr. Paul Nelson
Regulatory Affairs Specialist
325 Corporate Drive
Mahwah, New Jersey 07430

Re: K170771
Trade/Device Name: VariAx 2 Foot 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: March 10, 2017
Received: March 14, 2017

Dear Mr. Nelson:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K170771

Device Name
VariAx 2 Foot System

Indications for Use *(Describe)*

VariAx 2 Foot System is indicated for internal fixation of bones in the foot, ankle, hand, and wrist in adult and adolescent (12 - 21 years) patients, which includes replantation, joint fusions, corrective osteotomies, and 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.

510(k) Summary

Submitter: Stryker GmbH
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CH-2545 Selzach
Switzerland

Contact Person: Paul Nelson
Regulatory Affairs Specialist
Phone: (201) 831-5691
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Date Prepared: February 24, 2017

Name of Device: VariAx 2 Foot System

Common or Usual Name: Bone Plates

Classification Name: Single/multiple component metallic bone fixation appliances and accessories
(21 CFR § 888.3030)

Regulatory Class: Class II

Product Codes: HRS

Primary Predicate: VariAx 2 System, K141992

Additional Predicates: Ortholoc 2.0/2.4 Plate & Ortholoc 2.0/2.4 Screw, K090692

Additional Predicates: Modular Mini Fragment LCP System, K063049

Description:

VariAx 2 Foot System is a system used for internal fixation applications and is composed of sterile and nonsterile plates, and instruments. This system also uses compatible instruments and compatible screws from other systems. These contoured plates are made of Grade II, commercially pure titanium, with Type II anodization. They are available in a variety of sizes and shapes, and are designed to accept locking and non-locking screws, as well as k-wires for temporary fixation during initial placement.

This submission extends K141992 by introducing additional plates, additional instruments, and expands the indications.

Indications for Use:

VariAx 2 Foot System is indicated for internal fixation of bones in the foot, ankle, hand, and wrist in adult and adolescent (12 - 21 years) patients, which includes replantation, joint fusions, corrective osteotomies, and osteopenic bone.

Summary of Technologies:

A comparison of the systems demonstrated that the subject VariAx 2 Foot System is substantially equivalent to the previously cleared VariAx 2 system, K141992, to the Ortholoc 2.0/2.4 Plate & Ortholoc 2.0/2.4 Screw system, K090692, and to the Modular Mini Fragment LCP System, K063049, in regards to intended use, material, design, and operating principles.

Performance Data:

Non-Clinical Testing

Comparative mechanical testing to predicate systems demonstrated substantial equivalence.

The following tests were performed:

- Dynamic Bending
- Static Stiffness

Testing demonstrated that the VariAx 2 Foot System is equivalent in mechanical performance to the predicate devices of the ORTHOLOC 2.0/2.4 Plate & Ortholoc 2.0/2.4 Screw system.

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

Clinical Testing

Clinical testing was not a requirement of this submission.

Conclusion:

With the exception of the additional components being introduced, the VariAx 2 Foot System described in this submission is identical to the previously cleared, and primary predicate, K141992. Compared to the Ortholoc 2.0/2.4 Plate & Ortholoc 2.0/2.4 Screw system, and to the Modular Mini Fragment LCP system reference predicates, the subject system shares similar intended use, patient population, and principles of operation, as well as similar technological characteristics and materials. Mechanical testing demonstrated that subject system performs as intended and at least as well as the predicates. Based on these attributes, the subject system is deemed substantially equivalent.