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

Stryker GmbH
Ms. Tina Mornak
Senior Regulatory Affairs Specialist
325 Corporate Drive
Mahwah, New Jersey 07430

June 22, 2017

Re: K170727
Trade/Device Name: VariAx 2 Compression Plating 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: June 14, 2017
Received: June 15, 2017

Dear Ms. Mornak:

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)*

K170727

Device Name
VariAx 2 Compression Plating System

Indications for Use *(Describe)*

The Stryker VariAx 2 Compression Plating System is indicated for internal fixation of fractures in the Radius, Ulna, Humerus, Clavicle, Distal tibia and Fibula, in patients with normal bone density and osteopenic bone, for the following indications:

- osteotomies, mal-unions, and non-unions
- single, segmental, and comminuted 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

510(k) Summary

Proprietary Name:	VariAx 2 Compression Plating System
Common Name:	Plate, Fixation, Bone
Regulation Description:	Single/multiple component metallic bone fixation appliances and accessories
Regulation Number:	21 CFR 888.3030
Product Code:	HRS
Device Class:	Class II
Sponsor:	Stryker GmbH Bohnackerweg 1 2545 Selzach / Switzerland
Contact Person:	Tina Mornak Senior Regulatory Affairs Specialist 325 Corporate Drive Mahwah, NJ 07430 tina.mornak@stryker.com Phone: 201-831-6365 Fax: 201-831-6500
Date Prepared:	March 6, 2017
Primary Predicate:	Stryker GmbH VariAx2 Compression Plating System, K140565
Reference Devices:	Synthes Small Fragment DCL System, K000684

Description

This Traditional 510(k) submission is being supplied to the U.S. FDA to provide authorization to market additional components and expand the indications for use to the VariAx 2 Compression Plating System, previously cleared in K130009 and K140565. The VariAx 2 Compression Plating System is an internal fixation device that consists of various plates used with compatible screws to fit different types of fractures in the radius, ulna, humerus, clavicle, distal tibia and fibula. The subject components will be available sterile and non-sterile. The plates will be available in sizes ranging from 30-271mm in length.

Indications for Use

The Stryker VariAx 2 Compression Plating System is indicated for internal fixation of fractures in the Radius, Ulna, Humerus, Clavicle, Distal tibia and Fibula, in patients with normal bone density and osteopenic bone, for the following indications:

- osteotomies, mal-unions, and non-unions
- single, segmental, and comminuted fractures

Summary of Technologies

A comparison of the systems demonstrated that the subject VariAx 2 Compression Plating System is substantially equivalent to the Stryker GmbH VariAx2 Compression Plating System, K140565 and Synthes Small Fragment DCL System, K000684 in regards to intended use, material, design, and operational principles.

Non-Clinical Testing

Non-clinical laboratory testing was performed for the VariAx 2 Compression Plating System. The following tests were performed:

- LAL testing has been performed to establish that the subject device meets the specified 20EU/device limit
- MR Compatibility:
    - Magnetically Induced Displacement Force per ASTM F2052
    - Magnetically Induced Torque per ASTM F2213
    - Heating by RF Fields per ASTM F2182
    - Image Artifacts per ASTM F2119

An engineering rationale has been provided to demonstrate equivalence of the subject device to the predicate with respect to static and dynamic bending strength.

Clinical Testing

Clinical testing was not required for this submission.

Conclusion

The subject VariAx 2 Compression Plating System is substantially equivalent to the Stryker GmbH VariAx2 Compression Plating System, K140565 and Synthes Small Fragment DCL System, K000684.