DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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August 6, 2015

Stryker GmbH.
Dr. Heike Gustke
Regulatory Affairs Specialist
Prof. - Kuentscher - Str. 1-5
24232 Schoenkirchen, Schleswig-Holstein
Germany

Re: K151879
Trade/Device Name: VariAx 2 One-Third Tubular 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: July 6, 2015
Received: July 9, 2015

Dear Dr. Gustke:

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" (21CFR 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 yours,

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)*

K151879

Device Name

VariAx 2 One-Third Tubular Plating System

Indications for Use *(Describe)*

The Stryker VariAx 2 One-Third Tubular Plating System is intended for internal fixation of fractures of the clavicle, scapula, olecranon, humerus, radius, ulna, pelvis, distal tibia, fibula, small bones in the ankle, fore, mid- and hind foot in adult patients.

Indications include the following:

- osteotomies, and non-unions
- fixation of fractures
- normal bone density 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.

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6 510(k) Summary

Proprietary Name:	VariAx 2 One-Third Tubular Plating System
Common Name:	Bone plates
Regulation Description:	Single/multiple component metallic bone fixation appliances and accessories
Regulation Number:	21 CFR 888.3030
Product Code:	HRS (Plate, Fixation, Bone)
Class:	Class II
Sponsor:	Stryker GmbH Bohnackerweg 1 2545 Selzach / Switzerland
Contact Person:	Dr. Heike Gustke Regulatory Affairs Specialist Prof.-Kuentscher-Str. 1-5 24232 Schoenkirchen / Germany heike.gustke@stryker.com Phone: +49 4348 702 637 Fax: +49 4348 702 8637
Date Prepared:	June 30, 2015

Description

This Special 510(k) submission is being supplied to the U.S. FDA seeking clearance for a device modification of VariAx 2 One-Third Tubular Plates previously cleared in K141204 (VariAx 2 One-Third Tubular Plating System). Modification includes a change of plate thickness and addition of grooves to the waist part of the plate to improve mechanical behavior.

The VariAx 2 One-Third Tubular Plating System is an internal fixation device that consists of straight plates used with compatible screws to fit different types of fractures in the clavicle, scapula, olecranon, humerus, radius, ulna, pelvis, distal tibia, fibula, small bones in the ankle,

fore, mid- and hind foot in adult patients. The subject components will be available sterile and non-sterile. The plates will be available in sizes ranging from 23-191mm in length.

Intended Use

The Stryker Variax 2 One-Third Tubular Plating System is intended for internal fixation of bones in adult patients.

Indications for Use

The Stryker VariAx 2 One-Third Tubular Plating System is intended for internal fixation of fractures of the clavicle, scapula, olecranon, humerus, radius, ulna, pelvis, distal tibia, fibula, small bones in the ankle, fore, mid- and hind foot in adult patients.

Indications include the following:

- osteotomies, and non-unions
- fixation of fractures
- normal bone density and osteopenic bone

Summary of Technologies

Device comparison demonstrated that the subject device is substantially equivalent to the previously cleared VariAx 2 One-Third Tubular Plating System (K141204) in regards to intended use, indications for use, material, and operational principles as well as similar in regards to design for internal fixation of bones in adult patients.

Non-Clinical Test

A risk analysis was performed according to the requirements of DIN EN ISO 14971 ‘Medical devices - Application of risk management to medical devices’. Records of risk analysis process are retained in design history file. The evaluation demonstrated that the subject device did not present a new worst case and that the same verification and validation methods were applied to the subject device in comparison to the previously cleared predicate device (K141204). The analyses demonstrated that the subject device met the performance requirements and is as safe and effective as the predicate device.

Clinical Testing

Clinical testing was not required for this submission.

Conclusion

The VariAx 2 One-Third Tubular Plating System is substantially equivalent to the predicate device identified in this premarket notification.