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

June 4, 2018

Re: K180500
Trade/Device Name: VariAx 2 System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC
Dated: April 26, 2018
Received: April 27, 2018

Dear Paul 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.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Katherine D. Kavlock -S

for
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)*

K180500

Device Name
VariAx 2 System

Indications for Use *(Describe)*

The VariAx 2 System is indicated for adult and pediatric patients, where the implant would not cross open growth plates, for the treatment of normal or osteopenic bone for the following conditions or procedures:

- Fracture fixation, including single, segmental, and comminuted fractures
- Revision, including nonunion and malunion
- Intra- and extra-articular fractures
- Compression fracture
- Displaced fracture
- Reconstruction
- Replantation
- Arthrodesis
- Osteotomy

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

Submitter: Stryker GmbH
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Switzerland

Contact Person: Paul Nelson
Senior Regulatory Affairs Specialist
Phone: (201) 831-5691
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Date Prepared: February 2, 2018

Name of Device: VariAx 2 System

Common or Usual Name: Bone Screws

Classification Name: Smooth or threaded metallic bone fixation fastener
(21 CFR § 888.3040)

Regulatory Class: Class II

Product Codes: HWC

Subject: VariAx 2 System, K180500

Primary Predicate: VariAx 2 System, K173135

Additional Predicate: Profyle System, K062498

Description:

VariAx 2 is a system used for internal fixation applications and is composed of sterile and nonsterile screws, washers, and instruments. In addition to independent use, screws of this system are also used with compatible, internal fixation systems. These devices are made of titanium alloy, with Type III anodization, and are available in a variety of sizes and diameters, as well as locking and non-locking types.

Indications for Use:

The VariAx 2 System is indicated for adult and pediatric patients, where the implant would not cross open growth plates, for the treatment of normal or osteopenic bone for the following conditions or procedures:

- Fracture fixation, including single, segmental, and comminuted fractures
- Revision, including nonunion and malunion
- Intra- and extra-articular fractures
- Compression fracture
- Displaced fracture
- Reconstruction
- Replantation
- Arthrodesis
- Osteotomy

Summary of Technologies:

A comparison of the systems demonstrated that the subject VariAx 2 System is substantially equivalent to the previously cleared VariAx 2 system, K173135, and to the Profyle System, K062498, in regards to intended use, material, design, and operating principles.

Performance Data:

Non-Clinical Testing

Comparative mechanical testing to the predicate system demonstrated substantial equivalence.

The following tests were performed:

- Torque Strength
- Insertion Torque
- Pull-Out

Testing demonstrated that the VariAx 2 System is equivalent in mechanical performance to the predicate device of the Profyle System.

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

Clinical Testing

Clinical testing was not a requirement for this submission.

Conclusion:

The VariAx 2 System described in this submission has the same indications, intended use, target patient population, technological characteristics, and materials as the predicate devices. The mechanical testing demonstrates the performance of the proposed devices is equivalent to the predicate devices.