August 23, 2019

Stryker GmbH
Sanja Jahr
Senior Regulatory Affairs Specialist
325 Corporate Drive
Mahwah, New Jersey 07430

Re: K191412
Trade/Device Name: VariAx 2 System, VariAx 2 Mini Fragment System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC, HRS
Dated: May 24, 2019
Received: May 28, 2019

Dear Sanja Jahr:

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,

Shumaya Ali, MPH
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

List of Cleared Devices in K191412

List of Cleared Devices in K191412

1. VariAx 2 Mini Fragment System
2. VariAx 2 System

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)*
K191412

Device Name
VariAx 2 Mini Fragment System

Indications for Use *(Describe)*
The VariAx 2 Mini Fragment System is indicated for fracture fixation, reconstruction, replantation, stabilization, reduction, fusions, osteotomies, mal-unions, and non-unions of small bones and small bone fragments including normal and osteopenic bones in adult and adolescent (12 – 21 years) patients. The system is also indicated for non-load bearing stabilization and reduction of bone fragments in long bones.

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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The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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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)*

K191412

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)

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510(k) Summary

Proprietary Name:
VariAx 2 Mini Fragment System
VariAx 2 System

Common Name:
Bone screw
Bone plate

Regulation Description:
Single/multiple component metallic bone fixation appliances and accessories.
Smooth or threaded metallic bone fixation fastener.

Regulation Number:
21 CFR 888.3030
21 CFR 888.3040

Product Code:
HRS
HWC

Device Class:
Class II

Sponsor:
Stryker GmbH
Bohnackerweg 1
2545 Selzach / Switzerland

Contact Person:
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325 Corporate Drive
Mahwah, NJ 07430
Phone: 201-831-6797
Fax: 201-831-6020

Date Prepared:
May 24, 2019

Predicate Device:
VariAx 2 Mini Fragment System
Primary Predicate: Smith & Nephew Variable-Angle Locking Mini-Fragment Plating System (K132886)

Reference Device: Synthes (USA) Modular Mini Fragment LCP System (K063049)

VariAx 2 System
Primary Predicate: VariAx 2 System (180500)

Description

The VariAx 2 Mini Fragment System is used for internal fixation applications and is composed of sterile and nonsterile plates. Additionally, the plates are provided in locking and non-locking options, as well as various lengths, thicknesses, and configurations.

The VariAx 2 System is 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 commercially pure titanium and 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

VariAx 2 Mini Fragment System
The VariAx 2 Mini Fragment System is indicated for fracture fixation, reconstruction, replantation, stabilization, reduction, fusions, osteotomies, mal-unions, and non-unions of small bones and small bone fragments including normal and osteopenic bones in adult and adolescent (12 – 21 years) patients. The system is also indicated for non-load bearing stabilization and reduction of bone fragments in long bones.

VariAx 2 System
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 VariAx 2 Mini Fragment System and the VariAx 2 System are substantially equivalent to the previously cleared Synthes (USA) Modular Mini Fragment LCP System (K063049), Smith & Nephew Variable-Angle Locking Mini-Fragment Plating System (K132886), and VariAx 2 System (K180500) in regard to intended use, material, design, and operational principles.

Non-Clinical Testing

Comparative mechanical testing to the predicate system demonstrated substantial equivalence. The following tests were performed:

- Torsion

- Insertion Torque
- Pull-out
- Four-point bending

The aforementioned testing demonstrated that the VariAx 2 Mini Fragment System and the VariAx 2 System are substantially equivalent to the predicate devices. Additionally, MR assessments of magnetically-induced displacement force, magnetically-induced torque, RF-induced heating, and image artifacts demonstrate that the VariAx 2 Mini Fragment System and the VariAx 2 System are MR conditional.

Clinical Testing

This submission does not require clinical testing.

Conclusion

The VariAx 2 Mini Fragment System and the VariAx 2 System described in this submission have 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.