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

February 21, 2017

Stryker GmbH
Irene Bacalocostantis, PhD
Regulatory Affairs Specialist
325 Corporate Drive
Mahwah, New Jersey 07430

Re: K162841
Trade/Device Name: VariAx Distal Radius Plate System,
VariAx 2 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, HWC
Dated: January 17, 2017
Received: January 18, 2017

Dear Dr. Bacalocostantis:

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)*
K162481

Device Name

VariAx Distal Radius Plating System

Indications for Use *(Describe)*

The VariAx Distal Radius Plating System including the XXL Volar Distal Radius Plates is intended for internal fixation of small bone fractures, primarily including distal radius fractures.

Indications include:
- compression fractures
- intra-articular and extra-articular fractures
- displaced fractures

Following additional indications apply only for the XXL Volar Distal Radius Plates: Osteotomies, non-unions, and mal-unions.

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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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)*
K162841

Device Name
VariAx 2 System

Indications for Use *(Describe)*
The Stryker VariAx 2 System screws, when used in conjunction with VariAx Plating Systems; or used independently in a lag screw technique, are indicated for:
• Internal fracture fixation;
• Osteotomies;
• Revision procedures such as non-unions or mal-unions;

In addition, the following indications are specific to the devices listed below:

• T8 2.4mm Screws & T8 2.0mm Locking Peg: For use in small bones, primarily including the Distal Radius, in the treatment of:
o Compression fractures;
o Intra-articular and extra-articular fractures;
o Displaced fractures;
o Reconstruction procedures;
• T8 2.7mm Screws: For use in small bones, including the Distal Radius as well as the fore, mid- and hind Foot and Ankle, in the treatment of:
o Intra-articular and extra-articular fractures of the Distal Radius,
o Displaced and compression fractures of the Distal Radius;
o Replantation, joint fusions or arthrodesis and corrective osteotomies in the Foot & Ankle;
o Reconstruction procedures in the Foot & Ankle and Distal Radius;
• TI0 3.5mm and T10 2.7mm Screws: For use in the Radius, Ulna, Clavicle, Humerus, Foot and Ankle, Distal Tibia and Fibula, in the treatment of:
o Intra-articular and extra-articular fractures of the Distal Humerus and Proximal Ulna;
o Single, segmental and comminuted fractures;
o Replantation, joint fusions or arthrodesis and corrective osteotomies in the Foot & Ankle;
o Normal bone density or 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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510(k) Summary

Proprietary Name:	VariAx Distal Radius Plating System VariAx 2 System
Common Name:	Bone Plates Bone Screws
Regulation Number & Description:	21 CFR 888.3030; Single/multiple component metallic bone fixation appliances and accessories 21 CFR 888.3040; Smooth or threaded metallic bone fixation fastener
Product Code:	HRS (Plate, Fixation, Bone) HWC (Screw, Fixation, Bone)
Device Class:	Class II
Sponsor:	Stryker Trauma GmbH Bohnackerweg 1 2545 Selzach / Switzerland
Contact Person:	Irene Bacalocostantis Sr. Regulatory Affairs Specialist 325 Corporate Drive 07430 Mahwah / New Jersey irene.bacalocostantis@stryker.com Phone: +1 201 831 6797
Additional Contact Person:	Tina Mornak Sr. Regulatory Affairs Specialist tina.mornak@stryker.com Phone: +1 201 831 6365
Date Prepared:	December 13, 2016
Primary Predicate:	VariAx Distal Radius Plating System, K141430
Reference Predicate:	VariAx 2 System (screws), K140769

Description

This Traditional 510(k) submission is intended to provide information on a new packaging configuration of the VariAx Distal Radius Plates. The components of the VariAx Distal

Radius System remain identical to those in the most recently cleared in K141430. No new components have been added to the system.

Briefly, the VariAx Distal Radius Plating System consists of several different plates and screws manufactured from Commercially Pure Titanium Grade 2 (ASTM F67) and Titanium Alloy (ASTM F136), respectively. The VariAx 2 System (screws) (cleared under K140769) include a series of Titanium Alloy (ASTM F136) screws intended to be used across the entire VariAx line. The VariAx 2 T8 2.0 mm peg, T8 2.4 mm and T8 2.7 mm screws, and washer are specifically indicated for use with VariAx Distal Radius Plating System. All implants are provided sterile and non-sterile.

The new packaging configuration, called the VariAx 2 Xpress Distal Radius Kit, includes already cleared sterile packed VariAx Distal Radius Plates and VariAx 2 T8 2.7 mm screws along with single use class I exempt instrumentation.

Intended Use

The VariAx Distal Radius Plate System is intended for internal fixation of small bone fractures, primarily including distal radius fractures. The VariAx 2 System is intended for internal fixation.

Indications for Use

VariAx Distal Radius Plating System

The VariAx Distal Radius Plating System including the XXL Volar Distal Radius Plates is intended for internal fixation of small bone fractures, primarily including distal radius fractures.

Indications include:

- compression fractures
- intra-articular and extra-articular fractures
- displaced fractures

Following additional indications apply only for the XXL Volar Distal Radius Plates: Osteotomies, non-unions, and mal-unions.

VariAx 2 System

The Stryker VariAx 2 System screws, when used in conjunction with VariAx Plating Systems; or used independently in a lag screw technique, are indicated for:

- Internal fracture fixation;
- Osteotomies;
- Revision procedures such as non-unions or mal-unions;

In addition, the following indications are specific to the devices listed below:

- T8 2.4mm Screws & T8 2.0mmn Locking Peg: For use in small bones, primarily including the Distal Radius, in the treatment of:
    - Compression fractures;
    - Intra-articular and extra-articular fractures;
    - Displaced fractures;
    - Reconstruction procedures;

- T8 2.7mm Screws: For use in small bones, including the Distal Radius as well as the fore, mid- and hind Foot and Ankle, in the treatment of:
    - Intra-articular and extra-articular fractures of the Distal Radius,
    - Displaced and compression fractures of the Distal Radius;
    - Replantation, joint fusions or arthrodesis and corrective osteotomies in the Foot & Ankle;
    - Reconstruction procedures in the Foot & Ankle and Distal Radius;

- TI0 3.5mmn and T10 2.7mm Screws: For use in the Radius, Ulna, Clavicle, Humerus, Foot and Ankle, Distal Tibia and Fibula, in the treatment of:
    - Intra-articular and extra-articular fractures of the Distal Humerus and Proximal Ulna;
    - Single, segmental and comminuted fractures;
    - Replantation, joint fusions or arthrodesis and corrective osteotomies in the Foot & Ankle;
    - Normal bone density or osteopenic bone.

Summary of Technologies

There have not been any modifications made to the VariAx Distal Radius Plating System or the VariAx 2 System since clearance of the VariAx Distal Radius Plating System (K141430) and of the VariAx 2 System (K140769).

Non-Clinical Test

LAL testing has been performed to establish that the subject device meets the specified 20EU/device limit.

No additional non-clinical laboratory testing was required for this submission as there are no new components being added to the system.

Clinical Testing

Clinical testing was not required for this submission because there are no new components being added to the system.

Conclusion

This submission is only intended to introduce a new packaging configuration where the VariAx Distal Radius Plating System and VariAx 2 T8 2.7mm screws are packaged together. The VariAx Distal Radius System and the VariAx 2 System remain identical to the predicate system cleared under K141430 and K140769, respectively.