510(k) Summary JUL 18 2014

Proprietary Name:	VariAx Distal Radius Plating System
Common Name:	Bone Plates Bone Screws
Classification Name and Reference:	Single/multiple component metallic bone fixation appliance and accessories 21 CFR §888.3030 Smooth or threaded metallic bone fixation fastener 21 CFR §888.3040
Regulatory Class:	Class II
Product Codes:	HRS: Plate, Fixation, Bone HWC: Screw, Fixation, Bon
Sponsor:	Stryker Leibinger GmbH & Co.KG
Contact Person:	Elijah N. Wreh Regulatory Affairs Specialist 325 Corporate Drive Mahwah, NJ 07430 elijah.wreh@stryker.com Phone: 201-831-5691 Fax: 201-831-4691
Date Prepared:	May 29, 2014

Description

This Traditional 510(k) submission is being supplied to the U.S. Food and Drug Administration to provide authorization to market a line extension to the VariAx Distal Radius Plating, which was cleared in K04022, as the Universal Distal Radius System. The subject plate consists of distal radius fragment specific plates (lateral and dorsal medial). The subject components will be available sterile and non-sterile. The VariAx Distal Radius Plating System consists of multiple internal fixation plates in varying lengths and widths. The plates will be used with the VariAx locking screws, non-locking screws, locking pegs, and partially threaded screws previously cleared in K040022, K080667, K132502 and K140769.

Intended Use

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

Indications for Use

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 malunions.

Summary of Technologies

Device comparison showed that subject device is substantially equivalent to the TriMed Wrist Plates (K060041) in regards to intended use, and operational principles for use for internal fixation for fractures of the bones in the distal radius.

Non-Clinical Test

Non-clinical laboratory testing was performed on the worst case subject plates to determine substantial equivalence. The testing demonstrated that the subject plates being added to the VariAx Distal Radius Plating System are substantially equivalent to the TriMed Bone Plates (K060041). The following testing was performed "Standard Specification and Test Method for Metallic Bone Plates as per ASTM F382 – 99: 2008."

Clinical Testing

Clinical testing was not required for this submission.

Conclusion

The subject devices which are being added to the VariAx Distal Radius Plating System are substantially equivalent to the predicate device identified throughout this submission.

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

July 18, 2014

Stryker Leibinger GmbH & Co.KG
Mr. Elijah N. Wreh
Regulatory Affairs Specialist
325 Corporate Drive
Mahwah, New Jersey 07430

Re: K141430
Trade/Device Name: VariAx Distal Radius 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, HWC
Dated: May 29, 2014
Received: May 30, 2014

Dear Mr. Wreh:

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,

Lori A. Wiggins

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)* K141430

Device Name
VariAx Distal Radius Plating System

Indications for Use *(Describe)*

The VariAx Distal Radius Locking 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 malunions.

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)*

Elizabeth D. Frank -S

Division of Orthopedic Devices

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