DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

March 19, 2018

Stryker GmbH
Jackie Perri
Institutional Review Board Specialist
325 Corporate Drive
Mahwah, New Jersey 07430

Re: K172148
Trade/Device Name: Anchorage Bone 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 14, 2017
Received: July 17, 2017

Dear Jackie Perri:

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 (DICE) 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 (DICE) 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,

Vincent J. Devlin -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)*

K172148

Device Name

Anchorage Bone Plating System

Indications for Use *(Describe)*

The Anchorage Bone Plating System is indicated for stabilization and fixation of fresh fractures, revision procedures, joint fusion, and reconstruction of small bones in the hands, feet, wrists, ankles, fingers, and toes. The system may be used in adults and pediatric patients.

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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Stryker GmbH
Anchorage Bone Plating System

510(k) Summary

Proprietary Name: Anchorage Bone Plating System

Common Name: Plate/Screw, Fixation, Bone

Regulation Description: Single/Multiple component metallic fixation bone fixation appliance and accessories

Regulation Number: 21 CFR 888.3030

Product Code: HRS (Plate, Fixation, Bone)
HWC (Screw, Fixation, Bone)

Device Class: Class II

Sponsor: Stryker Trauma AG
Bohnackerweg 1
2545 Selzach / Switzerland

Contact Person: Jackie Perri
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325 Corporate Drive
Mahwah, NJ 07430
Phone: (732) 770-5616
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Date Prepared: June 13, 2017

Primary Predicate: Anchorage Bone Plating System (K083477)

Description

The Anchorage Bone Plating System includes single use bone fixation appliances intended to be permanently implanted. They are designed with different shape plates made from titanium alloy. The Anchorage Bone Plating System uses either a 3 mm or 3.5mm screws. The drill holes of the plates are aligned to assure the screws do not touch. The plates vary in curvature, length, thickness, number of holes, and plate shape. The Anchorage Bone Plating System is intended for fracture fixation.

Indications for Use

The Anchorage Bone Plating System is indicated for stabilization and fixation of fresh fractures, revision procedures, joint fusion, and reconstruction of small bones in the hands, feet, wrists, ankles, fingers, and toes. The system may be used in adults and pediatric patients.

Stryker GmbH
Anchorage Bone Plating System

Summary of Technologies

A comparison of the systems demonstrated that the subject Stryker Anchorage Bone Plating System is substantially equivalent to the predicate Memometal Anchorage Bone Plating System (K083477) in regards to intended use, material, design, and operational principles.

Non-Clinical Testing

Non-clinical laboratory testing was performed on the worst case subject screws to determine substantial equivalence. Mechanical testing was performed and demonstrated that Stryker Anchorage Bone Plating System is equivalent in mechanical performance to the predicate device, the Memometal Anchorage Bone Plating System (K083477).

The following testing was performed:

- Cantilever bending
- Torque to failure
- Push-Out
- Shear-off

Clinical Testing

Clinical testing was not required for this submission.

Conclusion

The subject Stryker Anchorage Bone Plating System is substantially equivalent to the predicate Memometal Anchorage Bone Plating System.