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 26, 2016

Stryker GmbH
Garry Hayeck, Ph.D.
Associate Manager, Regulatory Affairs
325 Corporate Drive
Mahwah, New Jersey 07430

Re: K160813
Trade/Device Name: EasyStep
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: JDR
Dated: June 24, 2016
Received: June 27, 2016

Dear Dr. Hayeck:

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 Parts 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,

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)*
K160813

Device Name
EasyStep

Indications for Use *(Describe)*
The EasyStep system is intended for bone fragment and osteotomy fixation of the foot in adult patients.
Indications include:
• Bone fragment fixation
• Osteotomy fixation

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)*

510(k) Summary

Submission Number: K160813

Proprietary Name: EasyStep

Common Name: Staple, fixation, bone

Regulation Description: Single/multiple component metallic bone fixation appliances and accessories

Regulation Number: 21 CFR 888.3030

Product Code: JDR

Device Class: Class II

Sponsor:
Stryker GmbH
Bohnackerweg 1
2545 Selzach / Switzerland

Contact Person:
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Date Prepared: July 22, 2016

Primary Predicate: Biomedical Enterprises Inc. Memograph Staple System (K993714)

Description

The Stryker GmbH EasyStep system includes superelastic staples fabricated from Nitinol (Nickel-Titanium alloy) per ASTM F 2063. The staples range in size from 4 mm to 12 mm in 2 mm increments where the staple size refers to the step size associated with each staple. The legs of each staple are barbed to provide anchorage within the bone fragments. All implants within the system are provided sterile.

Indications for Use

The EasyStep system is intended for bone fragment and osteotomy fixation of the foot in adult patients.
Indications include:
- Bone fragment fixation
- Osteotomy fixation

Summary of Technologies

A comparison of the systems demonstrated that the subject EasyStep system is substantially equivalent to the Biomedical Enterprises Inc. Memograph Staple System in regards to intended use, material, design, and operational principles.

Non-Clinical Testing

Non-clinical laboratory testing was performed on the worst case subject staples to determine substantial equivalence. Testing demonstrated that the EasyStep system is equivalent in mechanical performance to the predicate device, the Biomedical Enterprises, Inc. Memograph Staple System.

The following testing was performed:

- Pull-Out Testing per ASTM F564
- Four-Point Bending Testing per ASTM F564
- Cyclic Potentiodynamic Polarization (Corrosion) Test per ASTM F2129
- Bacterial Endotoxins Test (BET) per ANSI/AAMI ST72

Testing to determine the compatibility of the EasyStep system in an MR environment was also performed. These tests included an assessment of:

- Magnetically Induced Displacement Force per ASTM F2052
- Magnetically Induced Torque per ASTM F2213
- Heating by RF Fields per ASTM F2182
- Image Artifacts per ASTM F 2119

Clinical Testing

Clinical testing was not required for this submission.

Conclusion

The subject EasyStep system is substantially equivalent to the predicate Biomedical Enterprises Inc. Memograph Staple System.