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

August 6, 2015

Medline Industries, Incorporated
Ms. Jennifer Mason
Senior Regulatory Affairs Specialist
1 Medline Place
Mundelein, Illinois 60060

Re: K151235
Trade/Device Name: Medline Foot Plates and Screws
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 8, 2015
Received: May 11, 2015

Dear Ms. Mason:

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,

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)*
K151235

Device Name
Medline Foot Plates and Screws

Indications for Use *(Describe)*
The Medline Foot Plates and Screws are intended for use in stabilization and fixation of fresh fractures, revision procedures, joint fusion and reconstruction of bones of the feet and toes. Specific examples include:

- Arthrodesis of the first metatarsalcuneiform joint (Lapidus Fusion)
- Arthrodesis of the first metatarsophalangeal joint (MTP) including:
- Primary MTP Fusion due to hallux ridgidus and/or hallux valgus
- Revision MTP Fusion
- Revision of failed first MTP Arthroplasty implant

Flatfoot Osteotomies:
- Lateral Column Lengthening (Evans Osteotomy)
- Plantar Flexion Opening Wedge Osteotomy of the Medial Cuneiform (Cotton Osteotomy)
- Medial Displacement Calcaneal Osteotomy (MDCO)

Midfoot / Hindfoot Fusions:
- LisFranc Arthrodesis and/or Stabilization
- 1st(Lapidus), 2nd, 3rd, 4th, and 5th Tarsometatarsal (TMT) Fusions
- Intercuneiform Fusions
- Navicular-Cuneiform (NC) Fusion
- Talo-Navicular (TN) Fusion
- Calcaneo-Cuboid (CC) Fusion
- Medial Column Fusions (NC and 1st TMT)

The Medline Locking and Non-Locking Cortical Screws are indicated for use with the Medline Foot Plates of the same base material. The Non-Locking Cortical Screws are also indicated for bone reconstruction, osteotomy, arthrodesis, joint fusion, fracture repair, and fracture fixation, appropriate for the size of the device.

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.

Medline Industries, Inc.
One Medline Place
Mundelein, IL 60060

SECTION 5
510(k) SUMMARY
[AS REQUIRED BY 21CFR807.92(c)]

Submitter / 510(k) Sponsor
Medline Industries, Inc.
1 Medline Place
Mundelein, IL 60060

Registration Number: 1417592

Contact Person
Jennifer Mason
Senior Regulatory Affairs Specialist
Phone: 847-643-3652
Email: jamason@medline.com

Summary Preparation Date
July 31, 2015

Type of 510(k) Submission
Traditional

Device Name / Classification
Name of Device: Medline Foot Plates and Screws
Proprietary Name: Medline Foot Plates and Screws
Common Name: Plate, Fixation, Bone
Classification Number: 21 CFR 888.3030 – Class II
Classification Name: Single/multiple component metallic bone fixation appliances and accessories
Product Code: HRS: Plate, Fixation, Bone
HWC: Screw, Fixation Bone
Classification Panel: Orthopedics

Predicate Device
WRIGHT MEDICAL ORTHOLOC™ 3Di System
K121651 (Primary) – ORTHOLOC™ 3Di Midfoot/Flatfoot System (Wright Midfoot/Flatfoot System)

Medline Industries, Inc.
One Medline Place
Mundelein, IL 60060

Device Description

The Medline Foot Plates and Screws are manufactured from Titanium Alloy. The System includes plates offered in various styles, sizes and options; each contoured for specific anatomy and designed for specific procedures, and 2.7mm and 3.5mm diameter locking and non-locking cortical screws to be used with the polyaxial locking holes and compression slots included in the plates. The non-locking cortical screws can also be used for bone reconstruction, osteotomy, arthrodesis, joint fusion, fracture repair, and fracture fixation, appropriate for the size of the device. The system also includes reusable instrumentation necessary to implant the plates and screws, e.g. drill guides, tissue protectors, and drill bits. The Medline Foot Plates and Screws are within the currently marketed sizes and indications of the identified predicate devices.

Indications for Use

The Medline Foot Plates and Screws are intended for use in stabilization and fixation of fresh fractures, revision procedures, joint fusion and reconstruction of bones of the feet and toes. Specific examples include:

•Arthrodesis of the first metatarsalcuneiform joint (Lapidus Fusion)
•Arthrodesis of the first metatarsophalangeal joint (MTP) including:
• Primary MTP Fusion due to hallux ridgidus and/or hallux valgus
• Revision MTP Fusion
• Revision of failed first MTP Arthroplasty implant

Flatfoot Osteotomies:
• Lateral Column Lengthening (Evans Osteotomy)
• Plantar Flexion Opening Wedge Osteotomy of the Medial Cuneiform (Cotton Osteotomy)
• Medial Displacement Calcaneal Osteotomy (MDCO)

Midfoot / Hindfoot Fusions:
• LisFranc Arthrodesis and/or Stabilization
• 1st(Lapidus), 2nd, 3rd, 4th, and 5th Tarsometatarsal (TMT) Fusions
• Intercuneiform Fusions
• Navicular-Cuneiform (NC) Fusion
• Talo-Navicular (TN) Fusion
• Calcaneo-Cuboid (CC) Fusion
• Medial Column Fusions (NC and 1st TMT)

The Medline Locking and Non-Locking Cortical Screws are indicated for use with the Medline Foot Plates of the same base material. The Non-Locking Cortical Screws are also indicated for bone reconstruction, osteotomy, arthrodesis, joint fusion, fracture repair, and fracture fixation, appropriate for the size of the device.

Medline Industries, Inc.
One Medline Place
Mundelein, IL 60060

Summary of Technological Characteristics

The proposed device is substantially equivalent to the predicate devices. The Wright Medical ORTHOLOC™ 3Di System K121651, ORTHOLOC 3Di Hallux System K120359, ORTHOLOC™ 3Di Ankle Plating System and the Ortholoc Bone Screws K120802 were selected as the predicates based on the same intended use and same materials.

Summary of Non-Clinical Testing

Summary of Performance Testing

Test Type	Testing Standards	Performance Results
Static 4-Point Bending Testing (Plates)	ASTM F382	Equivalent to Predicate
Static Pullout Testing (Screws)	ASTM F543	Equivalent to Predicate
Static Torque Testing (Screws)	ASTM F543	Equivalent to Predicate

Static 4-Point Bend Testing

Static 4-point bend testing was conducted per ASTM F382-99 (2008). The purpose of this test was to ensure that the average load to failure of the proposed Medline Foot Plates was equivalent to the average load to failure bending stiffness of the predicate Wright Medical ORTHOLOC™ Plates.

Static Axial Pullout Testing

Static axial pullout testing was conducted per ASTM F543-13. The purpose of this test was to ensure that the axial pullout strength of the proposed Medline Locking Screws and Non-Locking Cortical Screws were equivalent to the pullout strength of the predicate Wright Medical ORTHOLOC™ Locking and Bone Screws.

Static Torque Testing

Static torque testing was conducted per ASTM F543-13. The purpose of this test was to ensure that the torsional strength of the proposed Medline Locking Screws and Non-Locking Cortical Screws were equivalent to the torsional strength of the predicate Wright Medical ORTHOLOC™ Locking and Bone Screws.

Conclusion

In accordance with 21 CFR Part 807, and based on the information provided in this premarket notification, Medline Industries, Inc. concludes that the Medline Foot Plates and Screws are safe, effective and substantially equivalent to the predicate, Wright Medical ORTHOLOC 3Di System (K 121651) as described herein.