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

December 9, 2016

Medline Industries, Inc.
Jennifer Mason
Senior Regulatory Affairs Specialist
One Medline Place
Mundelein, Illinois 60060

Re: K162829
Trade/Device Name: Medline UNITE® Ankle Fracture 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: October 5, 2016
Received: October 7, 2016

Dear Jennifer 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" (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,

Caroline Rhim -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)*
K162829

Device Name
Medline UNITE® Ankle Fracture Plating System

Indications for Use *(Describe)*
Medline UNITE® Ankle Fracture Plates and Screws are intended for fixation of fractures, osteotomies and nonunions of the distal tibia and fibula such as:

- Lateral Malleolar Fractures
- Syndesmosis Injuries
- Medial Malleolar Fractures
- Bi-Malleolar Fractures
- Tri-Malleolar Fractures
- Posterior Malleolar Fractures
- Distal Anterior Tibia Fractures
- Vertical Shear Fractures of the Medial Malleolous
- Pilon Fractures
- Distal Tibia Shaft Fractures
- Distal Fibula Shaft Fractures
- Distal Tibia Periarticular Fractures
- Medial Malleolar Avulsion Fractures
- Lateral Malleolar Avulsion Fractures

The Medline Locking and Non-Locking Cortical and Cancellous Screws are indicated for use with the Medline Ankle Fracture 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

K162829

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
December 8, 2016

Type of 510(k) Submission
Traditional

Device Name / Classification
Name of Device: Medline UNITE® Ankle Fracture Plating System
Proprietary Name: Medline UNITE® Ankle Fracture Plating System
Common Name: Plate, Fixation, Bone
Classification Name: Single/multiple component metallic bone fixation appliances and accessories
Product Code: HRS: Plate, Fixation, Bone
HWC: Screw, Fixation Bone
Classification Panel: Orthopedics
Regulatory Class: II
Regulation #: 21 CFR 888.3030

Predicate Device
The following 510(k) clearance letters (Appendix C), supporting this system, have been identified:
K011335 (Primary) - Synthes One Third Tubular Plate
K082072 - Synthes (USA) 3.5mm LCP Hook Plate
K091243 - ORTHOLOC™ Ankle Plating System
K102429 - ORTHOLOC™ 3Di Ankle Plating System and ORTHOLOC Bone Screws

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

K151235 – Medline Foot Plates and Screws
K130319 – Medline Cannulated Screws

Device Description

Medline UNITE® Ankle Fracture Plating System 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, 4.0mm Cancellous Screws, 4.0mm Medial Hook plate screws and 4.0mm Headed Cannulated screws to be used with the polyaxial locking holes and compression slots included in the plates. The system also includes reusable instrumentation necessary to implant the plates and screws, e.g. drill guides, tissue protectors, and drill bits. A comparison of the subject and predicate plates and screws is included below in Tables 2 through Tables 11. Additional detail regarding manufacturing process and product specifications can be found in Appendix B. The Medline Ankle Fracture Plates and Screws are within the currently marketed sizes and indications for use of the identified predicate devices.

Indications for Use

Medline UNITE® Ankle Fracture Plates and Screws are intended for fixation of fractures, osteotomies and nonunions of the distal tibia and fibula such as:

* Lateral Malleolar Fractures
* Syndesmosis injuries
* Medial Malleolar Fractures
* Bi-Malleolar Fractures
• Tri-Malleolar Fractures
• Posterior Malleolar Fractures
* Distal Anterior Tibia Fractures
• Vertical Shear Fractures of the Medial Malleolous
• Pilon Fractures
* Distal Tibia Shaft Fractures
* Distal Fibula Shaft Fractures
* Distal Tibia Periarticular Fractures
* Medial Malleolar Avulsion Fractures
* Lateral Malleolar Avulsion Fractures

The Medline Locking and Non-Locking Cortical and Cancellous Screws are indicated for use with the Medline Ankle Fracture 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. The Synthes One Third Tubular Plate K011335 was selected as the predicate based on the same intended use and similar materials.

Summary of Non-Clinical Testing

The following tests were performed in accordance with ASTM F382-14 standard to demonstrate substantial equivalence between the proposed Medline Ankle Fracture Plates and the primary predicate Synthes LCP One Third Tubular Plate.

Single Cycle 4-point Bend Testing

Single cycle 4-point bend testing was conducted per ASTM F382. The purpose of this test was to ensure that the bending stiffness of the proposed Medline Ankle Fracture Plates was equivalent to the bending stiffness of the predicate Synthes Plates, and to determine the 0.2% offset bending strength to be applied for fatigue testing.

Bending Fatigue Testing

Bending fatigue testing was performed per ASTM F382. The purpose of this test was to ensure that the fatigue life of the proposed Medline Ankle Plates was equivalent to that of the predicate, Synthes Plates.

Summary of Clinical Testing

Not applicable.

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 UNITE® Ankle Fracture Plating System is as safe and as effective as the predicate, the Synthes LCP One Third Tubular Plates.