March 2, 2022

Medline Industries, LP
Jennifer Mason
Senior Regulatory Affairs Specialist
Three Lakes Drive
Northfield, Illinois 60093

Re: K213567
Trade/Device Name: Medline UNITE® Calcaneal 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
Dated: January 6, 2022
Received: January 10, 2022

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Shumaya Ali, M.P.H.
Assistant Director
DHT6C: Division of Restorative, Repair
and Trauma Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213567

Device Name
Medline UNITE® Calcaneal Fracture Plating System

Indications for Use *(Describe)*
Medline UNITE® Calcaneal Fracture Plating System are intended for use in stabilization of fresh fractures, revision procedures, joint fusion, and reconstruction of bones in the feet and ankles including extra-articular, intra-articular, joint depression, tongue-type, and severely comminuted fracture of the calcaneus. The system can be used both in adult and pediatric (adolescent and child) 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Medline Industries, LP
Three Lakes Drive
Northfield, IL 60093

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

Submitter / 510(k) Sponsor
Medline Industries, LP
Three Lakes Drive
Northfield, IL 60093
Registration Number: 1417592

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

Summary Preparation Date
February 22, 2022

Type of 510(k) Submission
Traditional

Device Name / Classification
Trade Name: Medline UNITE® Calcaneal Fracture Plating System
Common Name: Plate, Fixation, Bone
Classification Name: Single/multiple component metallic bone fixation appliances and accessories
Product Code: HRS
Classification Panel: Orthopedic
Regulatory Class: Class II
Regulation Number: 21 CFR 888.3030

Predicate Device
Wright Medical ORTHOLOC® Calcaneal Plating System
K142121

Medline Industries, LP
Three Lakes Drive
Northfield, IL 60093

Reference Devices

Tornier Calcaneal Fracture Plate System
K090582

Medline Foot Plates and Screws
K151235

Device Description

The Medline UNITE® Calcaneal Fracture Plating System consists of 3 styles of Sinus Tarsi plates (Sinus Tarsi, Sinus Tarsi Offset, and Sinus Tarsi Extension) made from Titanium Alloy (Ti-6Al-4V ELI) and Perimeter plates made from Commercially Pure Titanium. The Sinus Tarsi, Sinus Tarsi Offset, and Sinus Tarsi Extension, and Perimeter plates are each offered in small, medium, and large sizes in left and right configurations. The plates can accommodate 2.7mm, 3.5mm and 4.0mm screws. Previously cleared 3.5mm locking and non-locking screws (K151235) that range from 10-60mm in length will be included in the tray with the Medline UNITE® Calcaneal Fracture Plates. The system also includes reusable instrumentation necessary to implant the plates and screws, e.g. targeting guide, drill guides, drill bits

Indications for Use

Medline UNITE® Calcaneal Fracture Plating System are intended for use in stabilization of fresh fractures, revision procedures, joint fusion, and reconstruction of bones in the feet and ankles including extra-articular, intra-articular, joint depression, tongue-type, and severely comminuted fracture of the calcaneus. The system can be used in both adult and pediatric (adolescent and child) patients.

Summary of Technological Characteristics

The proposed device is substantially equivalent to the predicate, Wright Medical ORTHOLOC® Calcaneal Plating System. A discussion of similarities and differences is listed below.

- Intended Use – identical. The subject device and the predicate device have the same intended use.
- Indications for Use – similar. The indications for use for the Medline UNITE® Calcaneal Fracture Plating System are more specific than the predicate, but still fall under the same intended use.
- Materials – similar. The proposed device and the predicate device are both made from CP4 titanium. The proposed device is also available in Ti-6Al-4V.
- Design Features – identical. Both the proposed plates and the predicate feature polyaxial locking to 15 degrees. Both plates can be used with 3.5mm locking and non-locking screws.
- Design Configurations – similar. The proposed plates and the predicate plates are both offered in left and right configurations. The predicate plates are reversible, whereas, the Medline plates are not.

Medline Industries, LP
Three Lakes Drive
Northfield, IL 60093

Summary of Non-Clinical Testing

Performance Testing (Bench)

The following tests were performed in accordance with ASTM F382 to demonstrate substantial equivalence between the proposed Medline UNITE® Calcaneal Fracture Plates and the predicate ORTHOLOC® Calcaneal Plates.

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 Unite® Calcaneal Plates were equivalent to the bending stiffness of the predicate Wright Medical Plates. The Medline Unite® Calcaneal Plates and the predicate Wright Medical ORTHOLOC® Calcaneal Plates are substantially equivalent in 4-point single cycle bend testing.

Bending Fatigue Testing

Bending fatigue testing was conducted per ASTM F382. The purpose of this test was to ensure that the bending fatigue of the proposed Medline Unite® Calcaneal Plates were equivalent to the bending fatigue of the predicate Wright Medical Plates. Results from this testing demonstrate that the Medline UNITE® Calcaneal Plates are substantially equivalent to the Wright Medical ORTHOLOC® CALC Fracture Plates in bending fatigue.

Performance Testing (Animal)

This section does not apply. No animal testing was performed.

Performance Testing (Clinical)

This section does not apply. No clinical testing was performed.

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 proposed Medline UNITE® Calcaneal Fracture Plating System is substantially equivalent to the predicate device, K142121 ORTHOLOC® Calcaneal Plating System.