January 24, 2023

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

Re: K222665
Trade/Device Name: Medline UNITE® Ankle Fusion 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: December 22, 2022
Received: December 22, 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 -S

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)*
K222665

Device Name
Medline UNITE® Ankle Fusion Plating System

Indications for Use *(Describe)*
The Medline UNITE® Ankle Fusion Plating System is indicated for use in arthrodesis of the ankle including tibiotalocalcaneal and tibiotalar joints and tibiocalcaneal arthrodeses, in conjunction with stabilization of fresh fractures, revision procedures, and reconstruction of bones in the feet and ankles.

The Medline UNITE® Locking and Non-Locking Cortical Screws are indicated for use with the Medline UNITE® Ankle Fusion 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. The system can be used in both adult and pediatric (adolescent and child) patients.

Medline UNITE® Ankle Fusion Plates and Screws used for the surgical treatment of pediatric patients should not cross an active growth plate as this may impede bone growth and development in skeletally immature patients. Implanted Medline UNITE® Ankle Fusion Plates and Screws, which span an active growth plate in a pediatric patient, should be considered for hardware removal after primary arthrodesis or bone healing has been achieved.

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.

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Medline Industries, LP
Three Lakes Drive
Northfield, IL 60093

K222665 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
Contact Person: Jennifer Mason, Principal Regulatory Affairs
Phone: 847-643-3652
Email: jamason@medline.com

Summary Preparation Date
January 24, 2023

Type of 510(k) Submission
Traditional

Device Name / Classification
Trade Name: Medline UNITE® Ankle Fusion Plating System
Common Name: Plate, Fixation, Bone
Screw, Fixation, Bone
Classification Name: Single/multiple component metallic bone fixation appliances and accessories
Smooth or threaded metallic bone fixation fastener
Product Code: HRS, HWC
Classification Panel: Orthopedics
Regulatory Class: Class II
Regulation Number: 21 CFR 888.3030 and 21 CFR 888.3040

Primary Predicate Device
Medline UNITE® Calcaneal Fracture Plating System
K213567

Predicate Device
ORTHOLOC 3 Di Ankle Fusion Plating System
K121425

Medline Industries, LP
Three Lakes Drive
Northfield, IL 60093

Predicate Device
Medline Foot Plates and Screws
K151235

Predicate Device
Paragon28 ParaLock Plating System
K140397

Device Description
The Medline UNITE® Ankle Fusion Plating System Plates and Screws are manufactured from Titanium Alloy (Ti-6Al-4V ELI). The system includes plates offered in various styles, sizes and options; each contoured for specific anatomy and designed for specific procedures, and 4.5mm and 5.5mm diameter locking and non-locking cortical screws to be used with the polyaxial locking holes and compression slots included in the plates. Additionally, several plates in the system can accommodate 3.5mm and 4.0mm locking and non-locking cortical screws. Previously cleared 3.5mm (K151235) and 4.0mm locking and non-locking cortical screws, ranging from 16-40mm will be included in the tray with the Medline UNITE® Ankle Fusion Plates. The system also includes reusable instrumentation necessary to implant the plates and screws, e.g. drills, drill guides, tissue protectors, targeting guides, targeting guide sleeves, and a tray.

Indications for Use
The Medline UNITE® Ankle Fusion Plating System is indicated for use in arthrodesis of the ankle including tibiotalocalcaneal and tibiotalar joints and tibiocalcaneal arthrodesis, in conjunction with stabilization of fresh fractures, revision procedures, and reconstruction of bones in the feet and ankles.

The Medline UNITE® Locking and Non-Locking Cortical Screws are indicated for use with the Medline UNITE® Ankle Fusion 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. The system can be used in both adult and pediatric (adolescent and child) patients.

Medline UNITE® Ankle Fusion Plates and Screws used for the surgical treatment of pediatric patients should not cross an active growth plate as this may impede bone growth and development in skeletally immature patients. Implanted Medline UNITE® Ankle Fusion Plates and Screws which span an active growth plate in a pediatric patient, should be considered for hardware removal after primary arthrodesis or bone healing has been achieved.

Summary of Technological Characteristics
The proposed device is substantially equivalent to the primary predicate, Medline UNITE® Calcaneal Fracture Plating System. A discussion of similarities and differences is listed below.

- Intended Use – identical. Both the proposed device and the predicate device are intended for stabilization of fresh fractures, revision procedures, and reconstruction of bones in the fee and ankles.

- Indications for Use – similar. The indications for use of the subject device is identical to the indications for use of the predicate device, however, Medline is requesting to add more specific ankle indications that still fall under the original indications for use and do not result in a new intended use.

- Materials – identical. The proposed device and the predicate device are both from titanium alloy.

- Plate Configuration – identical. Both the proposed plates and the predicate plates are offered in both left/right and universal configurations.

- Design Features – similar. Both the proposed plates and the predicate plates feature polyaxial locking up to 15-degrees. The proposed plates also include compression slots.

- Screw Lengths and Diameters – similar. Both the subject screws and the predicate screws will be offered in 4.5 and 5.5mm diameters. The subject screws are longer than the primary predicate, however, the screws are not as long as the Wright Medical ORTHOLOC 3Di Ankle Fusion Screws.

Summary of Non-Clinical Testing

Performance Testing (Bench)

The subject Medline UNITE® Ankle Fusion Plates do not represent a new worst-case when compared to the previously cleared Medline UNITE® Calcaneal Fracture Plates (K213567). Additionally, mechanical testing of the subject Medline UNITE® Ankle Fusion Plates and the ParaLock Plates (K140397) demonstrated substantially equivalent mechanical performance of the subject devices. An engineering analysis was performed to determine the subject screws do not present a new worst-case for yield strength, axial pullout, and torsional strength when compared to the predicate Medline Foot Screws (K151235). Based on this analysis, the subject Medline UNITE® Ankle Fusion Plating System is substantially equivalent to the predicate devices.

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.

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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 Fusion Plating System are as safe and as effective for their intended use as the predicate device, Medline UNITE® Calcaneal Fracture Plating System (K213567).