September 27, 2022

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

Re: K221360
Trade/Device Name: Medline UNITE® Medial Malleolus Peg Plate 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: August 19, 2022
Received: August 26, 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,

For: 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)*
K221360

Device Name
Medline UNITE® Medial Malleolus Peg Plate System

Indications for Use *(Describe)*
The Medline UNITE® Medial Malleolus Peg Plate System, when used in conjunction with the Medline UNITE® Locking and Non-Locking Screws, are indicated for fixation of fractures, osteotomies, and nonunions of the distal tibia and fibula such as:

- Medial Malleolar Fractures
- Lateral Malleolar Fractures
- Syndesmosis Injuries
- Bi-Malleolar Fractures
- Tri-Malleolar Fractures
- Vertical Shear Fractures of the Medial Malleolus
- Medial Malleolar Avulsion Fractures
- Lateral Malleolar Avulsion Fractures

In addition, the Medline UNITE® Locking Pegs, when used in conjunction with the Medline UNITE® Mini Plates and Screws, are indicated for use in stabilization of fresh fractures, revision procedures, joint fusion and reconstruction of small bones of the hand, feet, wrist, ankles, fingers and toes. The system can be used in both 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.

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

Summary Preparation Date
August 5, 2022

Type of 510(k) Submission
Traditional

Device Name / Classification
Trade Name: Medline UNITE® Medial Malleolus Peg Plate 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: Orthopedic
Regulatory Class: Class II
Regulation Number: 21 CFR 888.3030
21 CFR 888.3040

Primary Predicate Device
Medline UNITE® Ankle Fracture Plating System
K162829

Medline Industries, LP
Three Lakes Drive
Northfield, IL 60093

Predicate Device

Stryker VariAx 2 System
K132502

Medline UNITE® Mini Plates and Screws
K181820

Reference Device

Medline Foot Plates and Screws
K151235

Device Description

The Medline UNITE® Medial Malleolar Peg Plate System consists of implants manufactured from Titanium Alloy (Ti-6Al-4V ELI). The system includes plates offered in two sizes. The plates can accommodate Ø2.7mm, Ø3.5mm, and Ø4.0mm locking and non-locking screws and Ø2.0mm locking pegs. The system also includes reusable instrumentation necessary to implant the plates, screws, and pegs, e.g. plate inserter, wire sleeve.

Indications for Use

The Medline UNITE® Medial Malleolus Peg Plate System, when used in conjunction with the Medline UNITE® Locking and Non-Locking Screws, are indicated for fixation of fractures, osteotomies, and nonunions of the distal tibia and fibula such as:

- Medial Malleolar Fractures
- Lateral Malleolar Fractures
- Syndesmosis Injuries
- Bi-Malleolar Fractures
- Tri-Malleolar Fractures
- Vertical Shear Fractures of the Medial Malleolus
- Medial Malleolar Avulsion Fractures
- Lateral Malleolar Avulsion Fractures

In addition, the Medline UNITE® Locking Pegs, when used in conjunction with the Medline UNITE® Mini Plates and Screws, are indicated for use in stabilization of fresh fractures, revision procedures, joint fusion and reconstruction of small bones of the hand, feet, wrist, ankles, fingers and toes. 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 primary predicate, Medline UNITE® Ankle Fracture Plating System. A discussion of similarities and differences is listed below.

- Intended Use – identical. The Medline UNITE Medial Malleolus Peg Plate System and the predicate device are both intended for fixation of fractures, osteotomies and nonunions of the distal tibia and fibula.

- Indications for Use – similar. The Medline UNITE® Medial Malleolus Peg Plate System has the same indications for use as the predicate device, however, the subject device has more narrowed indications in comparison.

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

- Design Features – similar. Both the proposed plates and the predicate device feature polyaxial locking up to 15 degrees. Both plates can be used with 2.7mm, 3.5mm and 4.0mm locking and non-locking screws.

- Design Configurations – similar. Both the Medline UNITE® Medial Malleolus Peg Plates and the predicate plates are offered in a universal configuration. Although the predicate plates are also offered in left and right configurations, whereas, the proposed plates are not.

- Peg Lengths – similar. The Medline UNITE® Medial malleolus Pegs will be offered in lengths of 10mm to 60mm. The predicate pegs are offered in lengths of 16mm to 26mm. Although the subject pegs are longer as compared to the predicate device, the 2.7mm, 3.5mm and 4.0mm Medline UNITE Foot Plating Screws which are being included as a reference device are available in lengths from 10mm up to 60mm.

- Peg Diameters – identical. The Medline UNITE® Medial Malleolus Pegs will be offered in a 2.0mm diameter which is the exact same diameter as the predicate VariAx 2 pegs.

Summary of Non-Clinical Testing

Biocompatibility Testing

The Medline UNITE® Medial Malleolus Peg Plate System is manufactured from titanium alloy conforming to ASTM F136 or ISO 5832-3. The subject device and the predicate device are both manufactured from the identical raw material using the same manufacturing process, therefore, biocompatibility testing was leveraged from the predicate submission to support biocompatibility on the subject device.

Performance Testing (Bench)

The subject device, the Medline UNITE® Medial Malleolus Peg Plate System, do not represent a new, worst-case when compared to the previously cleared Medline UNITE® Ankle Fracture Plating System. An engineering analysis was performed to determine that the subject screws do not present a new worst-case for

torsional yield strength when compared to the predicate. Based on this analysis, the subject device, Medline UNITE® Medial malleolus Peg Plate System, is substantially equivalent to the predicate, Medline UNITE® Ankle Fracture Plating System.

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 Medline UNITE® Medial Malleolus Peg Plate System are as safe and as effective for their intended use as the predicate device, the Medline UNITE® Ankle Fracture Plating System K162829.