January 18, 2024

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

Re: K234031
Trade/Device Name: Medline UNITE Ancillary Foot Recon 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 19, 2023
Received: December 20, 2023

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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)*
K234031

Device Name
Medline UNITE® Ancillary Foot Recon Plating System

Indications for Use *(Describe)*
The Medline UNITE® Ancillary Foot Recon Plating System is 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 UNITE® 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.

The Medline UNITE® Lisfranc Screws are intended to be used for fixation such as Lisfranc arthrodesis, first metatarsophalangeal arthrodesis, midfoot and hindfoot arthrodeses or osteotomies, fixation of osteotomies for hallux valgus treatment (Scarf and Chevron), and arthrodesis of the metatarsocuneiform joint to reposition and stabilize metatarsus primus varus.

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."

510(k) SUMMARY
[AS REQUIRED BY 21 CFR 807.92(c)]
K234031

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

Registration Number: 1417592

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

Summary Preparation Date
January 17, 2024

Type of 510(k) Submission
Special

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

Primary Predicate Device
Medline Foot Plates and Screws
K151235

Predicate Device
CHARLOTTE™ LisFranc Bone Screw & CHARLOTTE™ LisFranc Plate
K081374

Predicate Device Information

Medline Cannulated Screw
K130319

Device Description

The Medline UNITE® Ancillary Foot Recon 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, 2.7mm, 3.5mm, and 4.0mm diameter locking and non-locking cortical screws to be used with the polyaxial locking holes and compression slots included in the plates, 3.5mm crossplate screws to be used with the dual-mode compression slot(s) in select plates, and 3.7mm and 4.1mm solid Lisfranc screws. The system also includes reusable instrumentation necessary to implant the plates and screws, e.g. drill guides, tissue protectors, and drill bits. The Medline UNITE® Ancillary Plating System Plates and Screws are within the currently marketed sizes and indications of the identified predicate devices.

Indications for Use

The Medline UNITE® Ancillary Foot Recon Plating System is 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 UNITE® 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.

The Medline UNITE® Lisfranc Screws are intended to be used for fixation such as Lisfranc arthrodesis, first metatarsophalangeal arthrodesis, midfoot and hindfoot arthrodeses or osteotomies, fixation of osteotomies for hallux valgus treatment (Scarf and Chevron), and arthrodesis of the metatarsocuneiform joint to reposition and stabilize metatarsus primus varus.

Summary of Technological Characteristics

The proposed Medline UNITE® Ancillary Foot Recon Plating System and the predicate device(s) have a similar intended use.

The design features of the Medline UNITE® Ancillary Foot Recon Plates and Screws are compared to the predicate device(s) in the tables below.

TABLE 1: Comparison of Plates

Device Characteristic	Proposed Device	Predicate Device	Comparison Analysis
Product Name	Medline UNITE® Ancillary Foot Recon Plating System	Medline Foot Plates and Screws	N/A
510(k) Reference	N/A	K151235	N/A
Product Owner	Medline Industries, LP	Medline Industries, LP	Same
Product Code	HRS	HRS	Same
Regulation Number	21 CFR 888.3030	21 CFR 888.3030	Same
Materials - Plates	Titanium Alloy	Titanium Alloy	Same
Design Configurations	Left and Right, Universal	Left and Right	Similar
Design Features - Plates	Polyaxial Locking up to 15° Compression Slots	Polyaxial Locking up to 15° Compression Slots	Same

TABLE 2: Comparison of Plating Screws

Device Characteristic	Proposed Device	Predicate Device	Comparison Analysis
Product Name	Medline UNITE® Ancillary Foot Recon Plating System	Medline Foot Plates and Screws	N/A
510(k) Reference	N/A	K151235	N/A
Product Owner	Medline Industries, LP	Medline Industries, LP	Same
Product Code	HWC	HWC	Same
Regulation Number	21 CFR 888.3040	21 CFR 888.3040	Same
Materials	Titanium Alloy	Titanium Alloy	Same
Design Features	Locking and Non Locking	Locking and Non Locking	Same
Diameters	2.7mm, 3.5mm, 4.0mm	2.7mm, 3.5mm	Similar
Lengths	2.7mm: 10-60mm 3.5mm: 10-60mm 4.0mm: 14-60mm	2.7mm: 10-30mm 3.5mm: 10-60mm	Similar

TABLE 3: Comparison of LisFranc Screws

Device Characteristic	Proposed Device	Predicate Device	Predicate Device	Comparison Analysis
Product Name	Medline UNITE® Ancillary Foot Recon Plating System	CHARLOTTE LisFranc Bone Screw	Medline Cannulated Screws	N/A
510(k) Reference	N/A	K081374	K130319	N/A
Product Owner	Medline Industries, LP	Wright Medical Technology, Inc	Medline Industries, LP	Different
Product Code	HWC	HWC	HWC	Same
Regulation Number	21 CFR 888.3040	21 CFR 888.3040	21 CFR 888.3040	Same
Materials	Titanium Alloy	Stainless Steel	Titanium Alloy	Different
Design Features	Torx drive mechanism, Self-Tapping	Hex drive mechanism, Self-tapping	Torx drive mechanism, Self-Tapping	Similar
Diameters	3.7mm, 4.1mm	3.7mm, 4.5mm	2.0mm, 2.5mm, 3.0mm, 3.5mm, 4.0mm, 6.5mm, 7.5mm	Similar

Lengths	3.7mm: 20-100mm 4.1mm: 20-100mm	3.7mm: 20-50mm 4.5mm: 30-50mm	2.0mm: 10-24mm 2.5mm: 10-40mm 3.0mm: 10-40mm 3.5mm: 12-50mm 4.0mm: 14-50mm 6.5mm: 40-130mm 7.5mm: 40-130mm	Similar

Summary of Non-Clinical Testing

The subject Medline UNITE® Ancillary Foot Recon Plating System does not represent a new worst-case when compared to the previously cleared Medline Foot Plates and Screws (K151235).

An engineering analysis was performed to determine the subject Medline UNITE® Ancillary Foot Recon Plating System does not represent a new worst-case when compared to the previously cleared Medline Foot Plates and Screws (K151235) for bending and pullout strength. The results of this analysis demonstrate the subject Medline UNITE® Ancillary Foot Recon Plating System are substantially equivalent to the predicate Medline Foot Plates and Screws (K151235).

An engineering analysis was performed to determine the subject Medline UNITE® Ancillary Foot Recon Plating System does not represent a new worst-case when compared to the previously cleared Medline Foot Plates and Screws (K151235) for bending strength (plates) and axial pullout and torsional yield strength (screws). The results of this analysis demonstrate the subject Medline UNITE® Ancillary Foot Recon Plating System are substantially equivalent to the predicate Medline Foot Plates and Screws (K151235).

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.

Other Testing

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, LP. concludes that the Medline UNITE® Ancillary Foor Recon Plating System is as safe and as effective for their intended use as the predicate device Medline Foot Plates and Screws.