August 2, 2024

Medline Industries, LP
Jennifer Mason
Regulatory Affairs Principal
Three Lakes Drive
Northfield, Illinois 60030

Re: K241359
Trade/Device Name: Medline UNITE® MIS Foot Recon Screw System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC
Dated: May 13, 2024
Received: May 14, 2024

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K241359

Device Name

Medline UNITE® MIS Foot Recon Screw System

Indications for Use *(Describe)*

The Medline UNITE® MIS Foot Recon Screw System is indicated for the stabilization and fixation of bone reconstructions, osteotomies, joint fusions (arthrodeses), and fractures of short (tarsals) and long (metatarsals, phalanges, distal tibia and fibula) bones comprising the foot and ankle. Screws are intended for single use only.

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.

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Medline Industries, LP
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Northfield, IL 60093

K241359
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, Regulatory Affairs Principal
Phone: 847-643-3652
Email: jamason@medline.com

Summary Preparation Date
July 18, 2024

Type of 510(k) Submission
Traditional

Device Name / Classification
Trade Name: Medline UNITE® MIS Foot Recon Screw System
Common Name: Screw, Fixation, Bone
Classification Name: Smooth or threaded metallic bone fixation fastener
Product Code: HWC
Classification Panel: Orthopedics
Regulatory Class: Class II
Regulation Number: 21 CFR 888.3040

Predicate Device
Medline Cannulated Screw
K130319

Device Description
The Medline UNITE® MIS Foot Recon Screw System includes screws manufactured from Titanium Alloy (Ti-6Al-4V ELI) per ASTM F136 or IOS 5832-3. The screws are offered in various diameters from 2.5mm up to 4.0mm and overall lengths ranging from 14mm up to 70mm. The screws are single use and provided

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non-sterile intended to be cleaned and steam sterilized prior to use. The system also includes non-sterile, single use instrumentation necessary to implant the screws, e.g. drill bits and countersinks. Validated cleaning and sterilization instructions are included in the instructions for use.

Indications for Use

The Medline UNITE® MIS Foot Recon Screw System is indicated for the stabilization and fixation of bone reconstructions, osteotomies, joint fusions (arthrodeses), and fractures of short (tarsals) and long (metatarsals, phalanges, distal tibia and fibula) bones comprising the foot and ankle. Screws are intended for single use only.

Summary of Technological Characteristics

The proposed Medline UNITE® MIS Foot Recon Screw System and the predicate device have the same intended use.

The design features of the Medline UNITE® MIS Foot Recon Screw System are compared to the predicate, Medline Cannulated Screws (K130319) in the table below.

TABLE 1: COMPARISON OF PROPOSED AND PREDICATE DEVICES

Device Characteristic	Proposed Device	Predicate Device	Comparison Analysis
Product Name	Medline UNITE® MIS Foot Recon Screw System	Medline Cannulated Screw	Different
510(k) Reference	N/A	K130319	Different
Product Owner	Medline Industries, LP	Medline Industries, LP	Same
Product Code	HWC	HWC	Same
Intended Use	The Medline UNITE® MIS Foot Recon Screw System is indicated for the stabilization and fixation of bone reconstructions, osteotomies, joint fusions (arthrodeses), and fractures of short (tarsals) and long (metatarsals, phalanges, distal tibia and fibula) bones comprising the foot and ankle. Screws are intended for single use only.	The Medline Cannulated Screws are indicated for use in bone reconstruction, osteotomies, arthrodesis, joint fusion, fracture repair, and fracture fixation of bones appropriate for the size of the device. Screws are intended for single use only.	Same
Regulation Number	21 CFR 888.3040	21 CFR 888.3040	Same

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Screw Diameters	2.5mm, 3.0mm, 3.5mm, 4.0mm	2.0mm, 2.5mm, 3.0mm, 3.5mm, 4.0mm, 6.5mm, 7.5mm	Similar
Screw Lengths	2.5mm: 14-40mm 3.0mm: 14-50mm 3.5mm: 16-70mm 4.0mm: 20-70mm	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
Materials	Titanium Alloy	Titanium Alloy	Same
Design Features	Torx drive mechanism, self-tapping and self-drilling	Torx drive mechanism, self-tapping and self-drilling	Same
Sterile vs. Non-Sterile	Non-Sterile	Non-Sterile	Same
Disposable vs. Non-Disposable	Non-Disposable – Screw Implants Disposable - Drills and countersinks	Non-Disposable – Screw Implants	Similar
Single Use vs. Reusable	Single use	Single use	Same

Summary of Non-Clinical Testing

The subject Medline UNITE® MIS Foot Recon Screw System does not represent a new worst-case when compared to the previously cleared Medline Cannulated Screws.

- Torsional Yield Strength
  - The worst-case analysis predicted the subject screws, Medline UNITE® MIS Foot Recon Screw System (K241359), did not create a new worst-case compared to the predicate (K130319) with regard to torsional yield strength. However, testing per ASTM F543-23 was conducted to confirm the analysis. This is highlighted in the provided test reports (TR3270-001 Medline ASTM F543 Torsional Properties and Driving Torque Testing for 2.0mm Headed Screws Final Report.pdf, TR3270-002 Medline ASTM F543 Torsional Properties and Driving Torque Testing for 2.5mm PT Screws Final Report.pdf). The worst-case subject screws, Ø2.5mm PT screws (MSCP2526), were evaluated for torsional yield strength in accordance with ASTM F543-23 A1, exhibiting an average torsional yield strength of 0.66 N-m for six samples compared to the predicate screws, Ø2.0mm Headed Screws (MSD02016), which exhibited an average torsional yield strength of 0.50 N-m . The results from the Ø2.5mm PT Screws exceeds the FDA's Bone Screw SPBP Guidance (https://www.fda.gov/regulatory-information/search-fda-guidance-documents/orthopedic-

non-spinal-metallic-bone-screws-and-washers-performance-criteria-safety-and-performance), which is 0.6 N-m for a 2.5mm nominal major diameter screw

- Drive Torque
  - The subject screws, the driving and removal torque was only 6.36% of the torsional yield strength, which falls within the FDA's Bone Screw SPBP Guidance (https://www.fda.gov/regulatory-information/search-fda-guidance-documents/orthopedic-non-spinal-metallic-bone-screws-and-washers-performance-criteria-safety-and-performance) acceptance criteria of driving or removal torque being less than 50% of the torsional yield.
  - The worst-case subject screws were evaluated for drive torque (insertion, removal) in accordance with ASTM F543-23 Annex A2 and met the FDA'S Bone Screw Guidance acceptance criteria for driving torque being less than 50% of the torsional yield strength of the subject screw.
- Axial Pullout Strength
  - An engineering analysis was performed to evaluate the axial pullout strength of the worst-case subject screws. The results demonstrated substantially equivalent performance compared to the predicate, Medline Cannulated Screws (K130319) and met the FDA'S Bone Screw Guidance acceptance criteria for predicted shear failure force.

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, LP concludes that the Medline UNITE® MIS Foot Recon Screw System is as safe and as effective for their intended use as the predicate device, Medline Cannulated Screws (K130319).