April 11, 2025

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

Re: K243888
Trade/Device Name: Medline UNITE® REFLEX® Hybrid Nitinol Implant System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: JDR, HWC
Dated: March 12, 2025
Received: March 12, 2025

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

RYAN TROMBETTA -S

For: Limin Sun, Ph.D.
Assistant Director
DHT6A: Division of Joint
Arthroplasty 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)*

K243888

Device Name

Medline UNITE® REFLEX® Hybrid Nitinol Implant System

Indications for Use *(Describe)*

The Medline UNITE® REFLEX® Hybrid Nitinol Implants are intended to provide fixation for fractures, fusions or osteotomies of the bones of short (tarsals) and long (metatarsals, phalanges, distal tibia and fibula) bones comprising the foot and ankle such as: First metatarsalcuneiform arthrodesis, First metatarsophalangeal arthrodesis, Talo-Navicular Fusion, Lis-Franc arthrodesis, Scarf and Chevron osteotomies. Implants are intended for single use only.

The Medline UNITE® Locking and Non-Locking Cortical Screws are indicated for use with the Medline UNITE® REFLEX® Hybrid Nitinol Implant. 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.

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

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
April 10, 2025

Type of 510(k) Submission
Traditional

Device Name / Classification
Trade Name: Medline UNITE® REFLEX® Hybrid Nitinol Implant System
Common Name: Staple, 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: JDR, HWC
Classification Panel: Orthopedic
Regulatory Class: Class II
Regulation Number: 21 CFR 888.3030, 21 CFR 888.3040

Primary Predicate Device
Medline UNITE® REFLEX® Nitinol Staple System
K231885

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Predicate Devices

Medline UNITE® Ancillary Foot Recon Plating System
K234031

Medline UNITE® MIS Foot Recon Screw System
K241359

Medline UNITE® REFLEX® Dynamic Discs
K211612

Device Description

The Medline UNITE® REFLEX® Hybrid Nitinol Implants are manufactured from nickel titanium alloy (nitinol). The implants utilize chemical etching and passivation to form a protective oxidation layer on the outer surface. Chemical etching and passivation are common processes to create a uniform oxidation layer on the surface of the implant. The system includes implants offered in various styles, sizes, and options; each designed for specific anatomy and procedures. The implants can accommodate Ø2.7mm, Ø3.5mm, and Ø4.0mm locking and non-locking cortical screws to be used with the polyaxial locking holes and compression slots. The system also includes reusable and disposable instrumentation necessary for implantation of the REFLEX® Hybrid Nitinol Implant.

Indications for Use

The Medline UNITE® REFLEX® Hybrid Nitinol Implants are intended to provide fixation for fractures, fusions or osteotomies of the bones of short (tarsals) and long (metatarsals, phalanges, distal tibia and fibula) bones comprising the foot and ankle such as: First metatarsalcuneiform arthrodesis, First metatarsophalangeal arthrodesis, Talo-Navicular Fusion, LisFranc arthrodesis, Scarf and Chevron osteotomies. Implants are intended for single use only.

The Medline UNITE® Locking and Non-Locking Cortical Screws are indicated for use with the Medline UNITE REFLEX® Hybrid Nitinol Implant. 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.

Summary of Technological Characteristics

The proposed Medline UNITE® REFLEX® Hybrid Nitinol Implant System and the primary predicate device have the same intended use.

Medline Industries, LP
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The design features of the Medline UNITE® REFLEX® Hybrid Nitinol Implant System are compared to the predicate, Medline UNITE® REFLEX® Nitinol Staple System (K231885).

- Intended Use – same. Both the subject device and the primary predicate device are intended to provide fixation for fractures, fusions or osteotomies of the bones of the feet.

- Indications for Use – similar. The indications for use for the new proposed Medline UNITE® REFLEX® Hybrid Nitinol Implant System are identical to the original indications for use cleared in the primary predicate K231885. This new 510(k) includes additional indications covering locking and non-locking cortical screws used with the polyaxial locking holes and compression slots. These screws were cleared under K234031.

- Materials – same. Both the subject device and the primary predicate device are made from nickel titanium alloy (Nitinol) and meets the material specifications outlined in ASTM F2063.

- Leg Lengths – different. The primary predicate and subject devices are both offered in identical leg lengths of 16mm, 18mm, and 20mm. The new proposed device is also available in a 22mm leg length that is within the cleared range of lengths of the predicate device.

- Bridge Width – different. The primary predicate and subject devices are offered different bridge widths. The predicate device is offered in 1.5mm, 4mm, and 5mm widths, while the new proposed device is offered in 7.3mm and 10mm widths. The difference in bridge widths does not affect safety or effectiveness.

- Design features – Similar. Both the subject and primary predicate devices are offered in straight top configurations. This new proposed device also include polyaxial locking holes and compression slots that accept Ø2.7mm, Ø3.5mm, and Ø4.0mm locking and non-locking cortical screws. These additional design features do not affect safety or effectiveness.

- Sterility – same. The primary predicate and subject Medline UNITE® REFLEX® Hybrid Nitinol Implant System will be provided non-sterile and are intended to be steam sterilized at the healthcare facility prior to use.

Summary of Non-Clinical Testing

The subject Medline UNITE® REFLEX® Hybrid Nitinol Implants does not represent a new worst-case when compared to the previously cleared Medline UNITE® REFLEX® Nitinol Staples (K231885).

Medline Industries, LP
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An engineering analysis was performed to determine the subject Medline UNITE® REFLEX® Hybrid Nitinol Implants do not represent a new worst-case when compared to the previously cleared Medline UNITE® REFLEX® Nitinol Staples (K231885) for elastic static bending and axial pullout strength. The results of this analysis demonstrate the subject Medline UNITE® REFLEX® Hybrid Nitinol Implants are substantially equivalent to the predicate, Medline UNITE® REFLEX® Nitinol Staples (K231885).

To determine the worst-case staple for corrosion susceptibility representing the subject Medline UNITE® REFLEX® Hybrid Nitinol Implant, an additional engineering analysis was conducted. The results of this analysis and subsequent testing demonstrate the subject Medline UNITE® REFLEX® Hybrid Nitinol Implants are substantially equivalent to the predicate Medline UNITE® REFLEX® Nitinol Staples (K231885).

Performance Testing (Bench)

The following tests were performed to demonstrate substantial equivalence between the proposed Medline UNITE® REFLEX® Hybrid Nitinol Implants and the predicate Medline UNITE® REFLEX® Nitinol Staples (K231885).

Corrosion Susceptibility

Corrosion susceptibility testing was conducted per ASTM F2129 and the FDA guidance document *Technical Considerations for Non-Clinical Assessment of Medical Devices Containing Nitinol*. Testing was conducted to ensure that the proposed Medline UNITE® REFLEX® Hybrid Implants meet the predefined acceptance criteria. During testing, not all samples met the minimum acceptance criteria for electrostatic breakdown potential, so Nickel ion release testing was conducted.

Nickel-ion Release

Nickel ion release testing was conducted per ASTM F3306 and the FDA guidance document *Technical Considerations for Non-Clinical Assessment of Medical Devices Containing Nitinol*. Testing was conducted to ensure that the proposed Medline UNITE® REFLEX® Hybrid Implants meet the acceptance criteria. The total Ni-ion release and maximum daily Ni-ion release determined for any of the three (3) samples tested over 60-days was significantly lower than the FDA guidance for the Tolerable Intake (TI) value for parenteral (non-oral) exposure to nickel of 0.5 µg/kg/day, or 35 µg/day for a 70 kg adult.

Galvanic Corrosion

The Medline UNITE® REFLEX® Hybrid Nitinol Implants were tested for galvanic corrosion per ASTM F3044 “Standard Test Method for Evaluating the Potential for Galvanic Corrosion for Medical Implants”. The hybrid implants and screws representing the largest surface area ratio of the expected cathode material

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(titanium alloy) to the expected anode material (nitinol) were chosen for testing. Microscopic examination of all three (3) test samples revealed no pitting or indications of corrosion. The average calculated material release from mass loss, which includes both titanium alloy and nitinol materials, was significantly less than the FDA guidance for the Tolerable Intake (TI) value for parenteral (non-oral) exposure to nickel of 0.5 µg/kg/day, or 35 µg/day for a 70 kg adult.

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® REFLEX® Hybrid Nitinol Implants are as safe and as effective for their intended use as the predicate device, Medline UNITE® REFLEX® Nitinol Staple System (K231885).