August 9, 2023

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

Re: K231885
Trade/Device Name: Medline UNITE REFLEX Nitinol Staple 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
Dated: June 26, 2023
Received: June 27, 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 (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,

Limin Sun -S

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K231885

Device Name

Medline UNITE® REFLEX® Nitinol Staple System

Indications for Use *(Describe)*

The Medline UNITE® REFLEX® Nitinol Staples are intended to provide fixation for fractures, fusions or osteotomies of the bones of the hand and foot such as: First metatarsalcuneiform arthrodesis, First metatarsophalangeal arthrodesis, Talo-Navicular Fusion, LisFranc arthrodesis, Akin osteotomy, Scarf and Chevron osteotomies. Staples 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.

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."

Medline Industries, LP
Three Lakes Drive
Northfield, IL 60093

K231885
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, Principal Regulatory Affairs
Phone: 847-643-3652
Email: jamason@medline.com

Summary Preparation Date
August 8, 2023

Type of 510(k) Submission
Traditional

Device Name / Classification
Trade Name: Medline UNITE® REFLEX® Nitinol Staples
Common Name: Staple, Fixation, Bone
Classification Name: Single/Multiple Component Metallic Bone Fixation Appliances and Accessories
Product Code: JDR
Classification Panel: Orthopedics
Regulatory Class: Class II
Regulation Number: 21 CFR 888.3030

Predicate Device
Medline UNITE® REFLEX® Nitinol Staple System
K210482

Device Description
The Medline UNITE® REFLEX® Nitinol Staples are manufactured from nickel titanium alloy (Nitinol). The staples utilize chemical etching and passivation to form a protective oxidation layer on the outer surface. The system includes staples offered in a range of sizes from 8mm x 8mm to 30mm x 20mm. The

Medline Industries, LP
Three Lakes Drive
Northfield, IL 60093

Medline UNITE® REFLEX® Nitinol Staples are offered in different bridge lengths and include 2-leg and 4-leg staples. The system also includes reusable instrumentation necessary to implant the staples, e.g. drill guides, drills, locating pins, staple inserter, and tamp.

Indications for Use

The Medline UNITE® REFLEX® Nitinol Staples are intended to provide fixation for fractures, fusions or osteotomies of the bones of the hand and foot such as: First metatarsalcuneiform arthrodesis, First metatarsophalangeal arthrodesis, Talo-Navicular fusion, LisFranc arthrodesis, Akin osteotomy, Scarf and Chevron osteotomies. Staples are intended for single use only.

Summary of Technological Characteristics

The proposed device is substantially equivalent to the predicate device, the Medline UNITE® REFLEX® Nitinol Staple System. A discussion of similarities and differences is listed below.

TABLE 1: COMPARISON OF PROPOSED AND PREDICATE DEVICES

Device Characteristic	Proposed Device	Predicate Device	Comparison Analysis
Product Name	Medline UNITE® REFLEX® Nitinol Staple System	Medline UNITE® REFLEX® Nitinol Staple System	Same
510(k) Reference	TBD	K210482	N/A
Product Owner	Medline Industries, LP	Medline Industries, LP	Same
Product Code	JDR	JDR	Same
Indications for Use	The Medline UNITE® REFLEX® Nitinol Staples are intended to provide fixation for fractures, fusions or osteotomies of the bones of the hand and foot such as First metatarsalcuneiform arthrodesis, First metatarasophalangeal arthrodesis, Talo-Navicular fusion, LisFranc arthrodesis, Akin osteotomy, Scarf and Chevron osteotomies. Staples are intended for single use only.	The Medline UNITE® REFLEX® Nitinol Staples are intended to provide fixation for fractures, fusions or osteotomies of the bones of the hand and foot such as LisFranc arthrodesis, Akin osteotomy, Scarf and Chevron osteotomies. Staples are intended for single use only.	Similar
Regulation Number	21 CFR 888.3030	21 CFR 888.3030	Same
Design Features	Straight top configurations	Straight top configurations	Same

Medline Industries, LP
Three Lakes Drive
Northfield, IL 60093

Leg Lengths	8mm 10mm 12mm 14mm 15mm 16mm 18mm 20mm 25mm	8mm 10mm 12mm 15mm 20mm 25mm 27mm	Different
Legs	2-leg and 4-leg	2-leg	Different
Bridge Lengths	8mm 10mm 12mm 15mm 18mm 20mm 23mm 25mm 26mm 30mm	8mm 10mm 12mm 15mm 18mm 20mm 25mm	Different
Materials	Nickel Titanium Alloy	Nickel Titanium Alloy	Same
Surface Finish	Chemical etch and passivation	Chemical etch and passivation	Same
Manufacturing Process	Wire EDM and tumbling	Wire EDM and tumbling	Same
Instrumentation	Drill Bit 2.0mm, 3.0mm Drill Guide 8mm, 10mm, 12mm, 15mm, 18mm, 20mm, 23mm, 25mm Targeting Guide 26mm, 30mm Inserter MINI, MAX/ULTRA Sleeve 90 degree, 1.1mm, 1.4mm Pin 2.0mm, 3.0mm	Drill Bit 2.0mm Drill Guide 8mm, 10mm, 12mm, 15mm, 18mm, 20mm, 25mm Drill Guide 26mm Inserter MINI, MAX, ULTRA Pin 2.0mm, 3.0mm	Different
Prescription vs. OTC	Prescription Use	Prescription Use	Same
Sterile vs. Non-Sterile	Non-sterile	Non-sterile	Same

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

- Indications for Use – similar. The indications for use for the new proposed Medline UNITE® REFLEX® Nitinol Staple System are identical to the original indications for use cleared in

Medline Industries, LP
Three Lakes Drive
Northfield, IL 60093

K210482. This new 510(k) for the staples includes additional specific indications including: First metatarsalcuneiform arthrodesis, First metatarsophalangeal arthrodesis, Talo-Navicular fusion. These additional more specific indications are fractures, fusions, and osteotomies in the same anatomical locations. Therefore, these indications fall under the original indications for use and do not result in a new intended use.

- Design features – same. Both the new predicate and the subject staples are offered in straight top configurations.

- Leg Lengths – different. The predicate and subject devices are both offered in identical leg lengths of 8mm, 10mm, 12mm, 15mm, 18mm, 20mm and 25mm. The subject device is also available in 14mm and 16mm leg lengths that are within the cleared range of lengths of the predicate device.

- Staple legs – different. The predicate staple is available in a 2-leg design. The subject Medline UNITE® REFLEX® Nitinol Staple System will also be offered in a 2-leg design, as well as, a 4-leg design.

- Bridge Lengths – different. The predicate and subject 2-leg staples are both offered in identical lengths of 8mm, 10mm, 12, 15mm, 18mm, 20mm and 25mm. The subject 2-leg staple is also available in 23mm which is within the cleared range of lengths of the predicate device. The subject 4-leg staples will be offered in slightly longer lengths of 26mm and 30mm as well. The difference in bridge lengths does not affect safety or effectiveness of the devices.

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

- Surface Finish – same. The subject device and the predicate device have the same surface finish.

- Manufacturing Process – same. Both the subject device and the predicate device are manufactured using the exact same process.

- Instrumentation – different. Although both the subject device and the predicate device includes instrumentation necessary for implantation of the staples, some additional instruments and sizes are included in the subject device. The new instruments include drill guides and targeting guides, inserters, sleeves and pins.

Medline Industries, LP
Three Lakes Drive
Northfield, IL 60093

- Sterility – same. The predicate and subject Medline UNITE® REFLEX® Nitinol Staple 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® Nitinol Staples do not represent a new worst-case when compared to the previously cleared Medline UNITE® REFLEX® Nitinol Staples (K210482).

An engineering analysis was performed to determine the subject Medline UNITE® REFLEX® Nitinol Staples do not represent a new worst-case when compared to the previously cleared Medline UNITE® REFLEX® Nitinol Staples (K210482) for bending and pullout performance. The results of this analysis demonstrate the subject Medline UNITE® REFLEX® Nitinol Staples are substantially equivalent to the predicate Medline UNITE® REFLEX® Nitinol Staples (K210482).

To determine the worst-case staple for corrosion susceptibility representing the subject Medline UNITE® REFLEX® Nitinol Staple, an additional engineering analysis was conducted. The results of this analysis and subsequent testing demonstrate the subject Medline UNITE® REFLEX® Nitinol Staples are substantially equivalent to the predicted Medline UNITE® REFLEX® Nitinol Staples (K210482).

Performance Testing (Bench)

The following testing was performed to demonstrate substantial equivalence between the proposed Medline UNITE® REFLEX® Nitinol Staples and the predicate Medline UNITE® REFLEX® Nitinol Staples (K210482).

Engineering analysis was performed to compare the subject staple's bending strength/stiffness and pullout performance per ASTM F564 to the predicate staples (K210482).

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® Nitinol Staples meet the predefined acceptance criteria. All samples achieved electrostatic breakdown potential in excess of the minimum acceptance criteria, demonstrating acceptable corrosion susceptibility.

Performance Testing (Animal)

This section does not apply. No animal testing was performed.

Performance Testing (Clinical)

Medline Industries, LP
Three Lakes Drive
Northfield, IL 60093

This section does not apply. No clinical testing was performed.

Conclusion

Medline Industries, LP concludes that the subject Medline UNITE® REFLEX® Nitinol Staple System is as safe and as effective for their intended use as the predicate device the Medline UNITE® REFLEX® Nitinol Staple System (K210482).