April 22. 2021

Medline Industries, Inc.
Jennifer Mason
Regulatory Affairs Senior Specialist
Three Lakes Drive
Northfield, Illinois 60093

Re: K210482
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: February 5, 2021
Received: February 19, 2021

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,

Vesa Vuniqi
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K210482

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 : 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, Inc.
Three Lakes Drive
Northfield, IL 60093

510(k) SUMMARY
[AS REQUIRED BY 21CFR807.92(c)]

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

Registration Number: 1417592

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

Summary Preparation Date
March 2, 2021

Type of 510(k) Submission
Traditional

Device Name / Classification
Trade Name: Medline UNITE® REFLEX™ Nitinol Staple System
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
FuseForce Implant System
K124045

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 25mm x

Medline Industries, Inc.
Three Lakes Drive
Northfield, IL 60093

27mm. The Medline UNITE® REFLEX™ Nitinol Staples are offered in three different bridge widths. The MINI features a 1.5mm bridge width, the MAX has a 4.0mm bridge width and the ULTRA has a 5.0mm bridge width. **Table 1** below has a description of the staple sizes.

TABLE 1: Staple Descriptions

Staple	Bridge Widths	Bridge Lengths
Medline UNITE® REFLEX™ MINI Staples	1.5mm	8 x 8mm
		10 x 10mm
		12 x 12mm
Medline UNITE® REFLEX™ MAX Staples	4.0mm	15 x 15mm
		15 x 18mm
		18 x 18mm
		18 x 20mm
		20 x 20mm
Medline UNITE® REFLEX™ ULTRA Staples	5.0mm	20 x 20mm
		25 x 20mm
		25 x 25mm
		25 x 27mm

The MAX and ULTRA staples have a chamfer on the bridge that is not present on the MINI version of the staples. A comparison of the proposed and predicate staples is included below in **Tables 2 and 3**. The system includes reusable instrumentation necessary to implant the staples, e.g. drill guides, drill bits, pins and an inserter.

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 LisFranc arthrodesis, Akin osteotomy, Scarf and Chevron osteotomies. Staples are intended for single use only.

Summary of Technological Characteristics

TABLE 2: Comparison of Proposed and Predicate Devices

Device Characteristic	Medline UNITE® REFLEX™ Nitinol Staples (Proposed)	FuseForce Implant System (Predicate)
510(k)	TBD	K124045
Product Owner	Medline Industries, Inc.	Wright Medical Technology

Medline Industries, Inc.
Three Lakes Drive
Northfield, IL 60093

		(previously Solana Surgical, LLC)
Product Code	JDR	JDR
Regulation Number	21 CFR 880.3030	21 CFR 880.3030
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 LisFranc arthrodesis, Akin osteotomy, Scarf and Chevron osteotomies. Staples are intended for single use only.	The Solana Surgical, LLC FuseForce Implant System is 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

TABLE 3: Comparison of Proposed and Predicate Staples

Device Characteristic	Medline UNITE® REFLEX™ Nitinol Staples (Proposed)	FuseForce Implant System (Predicate)	Comparison
Materials	Nickel Titanium Alloy (Nitinol)	Nickel Titanium Alloy (Nitinol)	Identical
Design Feature	Straight top configuration	Straight top configurations	Identical
Leg Lengths	8mm 10mm 12mm 15mm 18mm 20mm 25mm 27mm	8mm 10mm 12mm 13mm and 15mm (offset) 15mm 16mm 20mm 22mm	Similar
Bridge Lengths	8mm 10mm 12mm 15mm 18mm 20mm 25mm	8mm 10mm 12mm 15mm 18mm 20mm 25mm	Identical
Sterile vs. Non-Sterile	Non-sterile	Sterile - gamma	Different

- Indications for Use – identical. The indications for use for the Medline UNITE® REFLEX™ Nitinol Staples are identical to the predicate device. Both staple systems are intended to provide

Medline Industries, Inc.
Three Lakes Drive
Northfield, IL 60093

fixation for fractures, fusions or osteotomies of the bones of the hand and foot such as LisFranc arthrodesis, Akin osteotomy, Scarf and Chevron osteotomies.

- Materials – identical. Both the subject device and the predicate device are made from nickel titanium alloy (Nitinol) per ASTM F2063.
- Design Features – identical. Both the Medline UNITE® REFLEX™ Nitinol Staples and the FuseForce staples feature a straight top design.
- Leg Lengths – similar. The subject device will be offered in sizes ranging from 8mm to 27mm. The predicate device leg lengths range from 8mm to 22mm.
- Bridge Lengths – identical. Both the Medline UNITE® REFLEX™ Nitinol Staples and the FuseForce staples are offered in the exact same lengths and range from 8mm to 25mm.
- Sterility – the subject device will be offered non-sterile intended to be sterilized by steam sterilization. The predicate FuseForce staples are provided sterile.

Summary of Non-Clinical Testing

The following tests were performed in accordance with ASTM F564 to demonstrate substantial equivalence between the proposed Medline UNITE® REFLEX™ Nitinol Staples and the predicate FuseForce Implant System.

Performance Testing (Bench)

The following tests were performed in accordance with ASTM F564 and ASTM F2129 to demonstrate substantial equivalence between the proposed Medline UNITE® REFLEX™ Nitinol Staples and the predicate FuseForce Implant System.

Elastic Static Bend Testing

Elastic static bend testing was conducted per ASTM F564.A4. Testing was conducted to ensure that the proposed Medline UNITE® REFLEX™ Nitinol Staples are equivalent to the predicate FuseForce Implant System in bending stiffness.

Constant Amplitude Bending Fatigue Testing

Constant amplitude bend fatigue testing was conducted per ASTM F564.A1. Testing was conducted to ensure that the proposed Medline UNITE® REFLEX™ Nitinol Staples are equivalent to the predicate Fuseforce Implant System in bending fatigue.

Medline Industries, Inc.
Three Lakes Drive
Northfield, IL 60093

Pull-Out Strength Testing

Pull-out strength testing was conducted per ASTM F564.A2. Testing was conducted to ensure that the proposed Medline UNITE® REFLEX™ Nitinol Staples are equivalent to the predicate Fuseforce Implant System in pull-out strength.

Corrosion Susceptibility Testing

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 criteria outlined in *Corrosion Testing of Medical Implants*[1]. The risk based acceptance criteria used to determine acceptable corrosion susceptibility for the proposed device, were that all samples achieved electrostatic breakdown potential(E_b) equal to or greater than +400mV.

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® REFLEX Nitinol Staple System is substantially equivalent to the predicate device, FuseForce Implant System.