October 19, 2023

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

Re: K232905
Trade/Device Name: Medline UNITE® REFLEX® Nitinol Staple Kit
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: September 18, 2023
Received: September 19, 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,

for Christopher Ferreira -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)*
K232905

Device Name
Medline UNITE® REFLEX® Nitinol Staple Kit

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.

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K232905
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
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Summary Preparation Date
September 18, 2023

Type of 510(k) Submission
Special

Device Name / Classification
Trade Name: Medline UNITE® REFLEX® Nitinol Staple Kit
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

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

Predicate Device
Medline UNITE® REFLEX® Nitinol Staple System
K210482

Predicate Device

Sniper Staple System
K162354

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. Chemical etching and passivation are common processes to create a uniform oxidation layer on the surface of the implant. The kits includes staples offered in a range of sizes from 8mm x 8mm to 25mm x 25mm. 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. The MAX and ULTRA staples have a chamfer on the bridge that is not present on the MINI version of the staples. **Table 1** below has a description of the staple sizes.

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.

Summary of Technological Characteristics

TABLE 1: COMPARISON OF PROPOSED AND PREDICATE DEVICES

Device Characteristic	Proposed Device	Primary Predicate Device	Predicate Device	Predicate Device	Comparison Analysis
Product Name	Medline UNITE® REFLEX® Nitinol Staple Kit	Medline UNITE® REFLEX® Nitinol Staple System	Medline UNITE® REFLEX® Nitinol Staple System	Trilliant Sniper Staple System	Same and Different
510(k) Reference	TBD	K231885	K210482	K162354	N/A
Product Owner	Medline Industries, LP	Medline Industries, LP	Medline Industries, LP	Trilliant Surgical, LTD	Same and Different
Product Code	JDR	JDR	JDR	JDR	Same
Intended Use	The Medline UNITE® REFLEX® Nitinol Staples are intended to provide fixation for fractures, fusions	The Medline UNITE® REFLEX® Nitinol Staples are intended to provide fixation for fractures, fusions	The Medline UNITE® REFLEX® Nitinol Staples are intended to provide fixation for fractures, fusions	The Trilliant Surgical Sniper Staple System is indicated for fixation of fractures and osteotomies of the	Primary Predicate – same Predicates – similar

	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.	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.	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.	hand, foot, and bones appropriate for the size of the device.	
Regulation Number	21 CFR 888.3030	21 CFR 888.3030	21 CFR 888.3030	21 CFR 888.3030	Primary Predicate – same Predicates – same
Design Features	Straight top configurations	Straight top configurations	Straight top configurations	Straight top configurations	Primary Predicate – same Predicates – same
Leg Lengths	8mm 10mm 12mm 15mm 18mm 20mm 25mm	8mm 10mm 12mm 14mm 15mm 16mm 18mm 20mm 25mm	8mm 10mm 12mm 15mm 18mm 20mm 25mm 27mm	8mm 10mm	Primary Predicate – similar Predicates – similar
Legs	2-leg	2-leg and 4-leg	2-leg	2-leg	Primary Predicate – similar Predicates – same
Bridge Lengths	8mm 10mm 12mm 15mm 18mm 20mm 25mm	8mm 10mm 12mm 15mm 18mm 20mm 23mm 25mm 26mm 30mm	8mm 10mm 12mm 15mm 18mm 20mm 25mm	8mm 10mm	Primary Predicate – similar Predicates – same and similar
Materials	Nickel Titanium Alloy	Nickel Titanium Alloy	Nickel Titanium Alloy	Nickel Titanium Alloy	Primary Predicate – same Predicate – same

Surface Finish	Chemical etch and passivation	Chemical etch and passivation	Chemical etch and passivation	Unknown	Primary Predicate – same Predicate – same
Manufacturing Process	Wire EDM and tumbling	Wire EDM and tumbling	Wire EDM and tumbling	Unknown	Primary Predicate – same Predicate – same
Instrumentation	Drill Bit Drill Guide Inserter Pin Tamp (class I) Akin Blade (class I)	Drill Bit Drill Guide Targeting Guide Inserter Sleeve Pin	Drill Bit Drill Guide Inserter Pin	Drill Bit / Post Drill Guide Inserter	Primary Predicate – similar Predicates – same and similar
Prescription vs. OTC	Prescription Use	Prescription Use	Prescription Use	Prescription Use	Primary Predicate – same Predicate – same
Sterile vs. Non-Sterile	Sterile	Non-sterile	Non-sterile	Sterile	Primary Predicate – different Predicate – different and same

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

- Indications for Use – same. The indications for use for the new proposed Medline UNITE® REFLEX® Nitinol Staple Kit are identical to the indications for use for the primary predicate device cleared in K231885.

- Design Features – same. Both the subject device and both the predicate staples are offered in straight top configurations.

- Leg Lengths – similar. The primary predicate and subject devices are both offered in identical leg lengths of 8mm, 10mm, 12mm, 15mm, 18mm, 20mm and 25mm. The K162354 staples are only offered in leg lengths of 8mm and 10mm.

- Staple Legs – similar. The staples in the Medline UNITE® REFLEX® Nitinol Staple Kit will be available in a 2-leg design only.

- Bridge Lengths – similar. The predicate and subject 2-leg staples are both offered in identical bridge lengths of 8mm, 10mm, 12mm, 15mm, 18mm, 20mm and 25mm. The K162354 staples are only offered in bridge lengths of 8mm and 10mm.

- Materials – same. Both the Medline UNITE® REFLEX® Nitinol Staple Kit and the predicate staples are manufactured from nickel titanium alloy (Nitinol) per ASTM F2063.

- Surface Finish – same. The staples in the Medline UNITE® REFLEX® Nitinol Staple Kit and the Medline UNITE® predicate staples have the same surface finish. The nitinol staples are chemical etched and passivated. The surface finish of the K162354 is unknown.

- Manufacturing Process – same. Both the subject device and the Medline UNITE® predicate devices are manufactured using the exact same process. The manufacturing process of the K162354 is unknown.

- Instrumentation – similar. Both the subject device and predicate devices have similar instrumentation for use with 2-leg staples, but does not include the 4-leg specific instrumentation in the primary predicate.

- Sterility – different and same. The predicate staples are provided non-sterile and intended to be cleaned and steam sterilized prior to use. The subject devices are sterile packed and sterilized via gamma sterilization. A sterilization validation was performed on the Medline UNITE® REFLEX® Nitinol Staple Kit to ensure the devices can be sterilized to a 10^{-6} sterility assurance level. In addition, a stability study was conducted to support a 5-year shelf life.

  The subject device and the K162354 predicate are both Nitinol bone staples sterilized using gamma radiation.

Summary of Non-Clinical Testing

The subject Medline UNITE® REFLEX® Nitinol Staple Kit do not represent a new worst-case when compared to the previously cleared predicate devices.

Performance Testing (Bench)

The following testing and engineering analyses were performed to demonstrate substantial equivalence between the proposed Medline UNITE® REFLEX® Nitinol Staple Kit and the predicate Medline UNITE® REFLEX® Nitinol Staples (non-sterile) cleared in K231885.

- Elastic Static Bend and Constant Amplitude Bending Fatigue Testing per ASTM F564
- Pullout Strength Testing per ASTM F564
- Corrosion Susceptibility Testing per ASTM F2129

- Bacterial endotoxin was evaluated using the Limulus Amebocyte Lysate (LAL) kinetic chromogenic assay. The testing demonstrated that the subject device meets the recommended maximum endotoxin level of 20 EU per device.

Results of the testing and engineering analyses demonstrate that the Medline UNITE® REFLEX® Nitinol Staples are substantially equivalent to the predicate devices.

The proposed Medline UNITE® REFLEX® Nitinol Staples were tested per ASTM F2129 and were found to be acceptable in corrosion susceptibility.

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® REFLEX® Nitinol Staple Kit is as safe and as effective for their intended use as the predicate devices.