December 10, 2021

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

Re: K211612
Trade/Device Name: Medline UNITE® REFLEX™ Dynamic Discs
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: HTN
Dated: September 1, 2021
Received: September 3, 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,

Shumaya Ali, MPH
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K211612

Device Name
Medline UNITE® REFLEX™ Dynamic Discs

Indications for Use *(Describe)*
The Medline UNITE® REFLEX™ Dynamic Discs 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. Discs 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."

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
November 22, 2021

Type of 510(k) Submission
Traditional

Device Name / Classification
Trade Name: Medline UNITE® REFLEX™ Dynamic Discs
Common Name: Washer, Bolt Nut
Classification Name: Washer, Bolt Nut
Product Code: HTN
Classification Panel: Orthopedic
Regulatory Class: Class II
Regulation Number: 21 CFR 888.3030

Primary Predicate Device
Medline Cannulated Screws
K130319

Reference Device
Medline UNITE® REFLEX™ Nitinol Staple System
K210482

Device Description

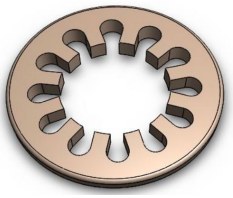
The Medline UNITE® REFLEX™ Dynamic Discs are manufactured from nickel titanium alloy (nitinol). The discs utilize chemical etching and passivation to form a protective oxidation layer on the outer surface. The discs are offered in various diameters and thicknesses to be used in conjunction with screws of various diameters.

Indications for Use

The Medline UNITE® REFLEX™ Dynamic Discs are indicated for use in bone reconstruction, osteotomies, arthrodesis, joint fusion and fracture repair and fracture fixation of bones appropriate for the size of the device. Discs are intended for single use only.

Summary of Technological Characteristics

TABLE 1: COMPARISON OF PROPOSED, PREDICATE AND REFERENCE DEVICES

Device Characteristic	Proposed Device	Predicate (Primary) Device	Reference Device	Comparison Analysis
Product Name	Medline UNITE® REFLEX™ Dynamic Discs	Medline Cannulated Screws	Medline UNITE® REFLEX™ Nitinol Staple System	Different
Photos of the Devices				N/A
510(k) Reference	K211612	K130319	K210482	Different
Product Owner	Medline Industries, Inc.	Medline Industries, Inc.	Medline Industries, Inc.	Same
Product Code	HTN	HWC	JDR	Different
Intended Use	The Medline UNITE® REFLEX™ Dynamic Discs are indicated for use in bone reconstruction, osteotomies, arthrodesis, joint fusion and fracture repair and fracture fixation of bones appropriate for the size of the device. Discs 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.	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.	Primary Predicate – Same Secondary Predicate – Similar

			Staples are single use only.	
Regulation Number	21 CFR 888.3030	21 CFR 888.3030	21 CFR 888.3030	Same
Design Features	Increases surface area of screw head	Increases surface area of screw head	N/A	Same
Design Configurations	Ø3.0 or 5.75mm Ø3.5 or 6.61mm Ø4.0 or 7.65mm Ø4.5 or 8.50mm Ø5.5 or 10.20mm Ø7.0 or 12.75mm	Ø2.0/Ø2.5 or 6.00mm Ø3.0/Ø3.5 or 8.00mm Ø4.0/Ø4.5 or 10.00mm Ø6.5 or 14.00mm Ø7.5 or 16.00mm	8 x 8mm 10 x 10mm 12 x 12mm 15 x 15mm 15 x 18mm 18 x 20mm 20 x 20mm 25 x 20mm 25 x 25mm 25 x 27mm	Different
Materials	Nickel Titanium Alloy	Titanium Alloy or Stainless Steel	Nickel Titanium Alloy	Primary Predicate – Different Secondary Predicate – Same
Prescription vs. OTC	Prescription	Prescription	Prescription	Same
Sterile vs. Non-Sterile	Non-Sterile	Non-Sterile	Non-Sterile	Same
Single Use vs. Reusable	Single Use Only	Single Use Only	Single Use Only	Same

The proposed modified device, Medline UNITE® REFLEX™ Dynamic Discs is substantially equivalent to the primary predicate, the Medline Cannulated Screws. A discussion of similarities and differences is listed below.

- Indications for use – same. The subject device, the Medline UNITE® REFLEX™ Dynamic Discs have the exact same indications for use as the Medline Cannulated Screws.

- Design Features – same. Both the subject device and the predicate device are intended to increase the surface area of the screw head.

- Design Configurations – similar. The Medline UNITE® REFLEX™ Dynamic Discs will be offered in sizes ranging from Ø3.0 to Ø7.0 whereas, the predicate device is offered in sizes Ø2.0 to Ø7.5. The subject device falls within the size range of the current Medline Cannulated Screws.

- Materials – different. The Medline UNITE® REFLEX™ Dynamic Discs are made from nitinol. The predicate device, is made from either stainless steel or titanium. To address this difference, a reference device has been provided, the Medline UNITE® RELEX™ Nitinol Staples, which are

made from the exact same nitinol material as the proposed Dynamic Discs. Testing was performed on the Dynamic Discs to ensure the nitinol meets the FDA guidance *Technical Considerations for Non-Clinical Assessment of Medical Devices Containing Nitinol*. The testing included determining the austenite finish (Af) temperature on final finished devices per ASTM F2004 and performing corrosion susceptibility testing per ASTM F2129.

Summary of Non-Clinical Testing

Transformation Temperature
Transformation testing was performed on the subject Medline UNITE® REFLEX™ Dynamic Discs using the DSC method per ASTM F2004 "Standard Test Method for Transformation Temperature of Nickel-Titanium Alloys by Thermal Analysis".

Galvanic Corrosion
The Medline UNITE® REFLEX™ Dynamic Discs were tested for galvanic corrosion per ASTM F3044 "Standard Test Method for Evaluating the Potential for Galvanic Corrosion for Medical Implants". The discs and screws representing the largest surface area ratio of the expected cathode material (titanium alloy) to the expected anode material (nitinol) were chosen for testing. Microscopic examination of all 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 CDRH recommended parenteral nickel limit value of 35µg/day for a 70kg adult.

Corrosion Susceptibility
Corrosion susceptibility testing was conducted per ASTM F2129 "Standard Test Method for Conducting Cyclic Potentiodynamic Polarization Measurements to Determine the Corrosion Susceptibility of Small Implant Devices". The discs, representing the worst-case in surface area, were tested as a construct with the screws implanted into Sawbones® to simulate in-vivo anatomic conditions. All samples achieved electrostatic breakdown potentials in excess of the minimum acceptance criteria, demonstrating acceptable corrosion susceptibility.

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™ Dynamic Discs are substantially equivalent to the predicate device, the Medline Cannulated Screws.