March 22, 2022

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

Re: K220511
Trade/Device Name: Medline UNITE® IM Fibula Implant
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC
Dated: February 15, 2022
Received: February 22, 2022

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, M.P.H.
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220511

Device Name
Medline UNITE® IM Fibula Implant

Indications for Use *(Describe)*
Medline UNITE® IM Fibula Implants 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. Implants 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.

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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, Senior Regulatory Affairs Specialist
Phone: 847-643-3652
Email: jamason@medline.com

Summary Preparation Date
March 21, 2022

Type of 510(k) Submission
Special

Device Name / Classification
Trade Name: Medline UNITE® IM Fibula Implant
Common Name: Screw, Fixation Bone
Classification Name: Smooth or threaded bone fixation fastener
Product Code: HWC
Classification Panel: Orthopedic
Regulatory Class: Class II
Regulation Number: 21 CFR 888.3040

Predicate Device
Medline Cannulated Screw:
K130319

Device Description
The Medline UNITE® IM Fibula Implants 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. The Medline UNITE® IM Fibula Implants are manufactured from Titanium Alloy per ASTM F136 and ISO 5832-3. The implants are offered in a 3.7/4.0mm tapered diameter with fully threaded lengths ranging from 65mm to 150mm. The implants are single use only and provided non-sterile.

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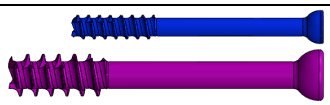
A comparison of the subject and predicate device is included below in Table 1 and additional detailed subject information can be found in **Appendix A** in the engineering drawings. The Medline UNITE® IM Fibula Implants are within the currently marketed sizes, diameter and length of the identified predicate device.

Indications for Use

Medline UNITE® IM Fibula Implants 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. Implants are intended for single use only.

Summary of Technological Characteristics

TABLE 1: COMPARISON OF PROPOSED AND PREDICATE DEVICES

Device Characteristic	Proposed Device	Predicate Device	Comparison Analysis
Product Name	Medline UNITE® IM Fibula Implants	Medline Cannulated Screws	Different
Product Photos			N/A
510(k) Reference	N/A	K130319	Different
Product Owner	Medline Industries, LP (previously Medline Industries, Inc.)	Medline Industries, Inc.	Same
Product Code	HWC	HWC	Same
Intended Use	Medline UNITE® IM Fibula Implants 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. Implants are intended for single use only.	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.	Same
Regulation Number	21 CFR 888.3040	21 CFR 888.3040	Same
Materials	Titanium Alloy	Titanium Alloy	Same
Sizes	3.7/4.0 x 65mm 3.7/4.0 x 70mm 3.7/4.0 x 75mm 3.7/4.0 x 80mm 3.7/4.0 x 85mm 3.7/4.0 x 90mm	Ø2.0 x 10-24mm Ø2.5 x 10-40mm Ø3.0 x 10-40mm Ø3.5 x 12-50mm Ø4.0 x 14-50mm Ø4.5 x 14-70mm	Different

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	3.7/4.0 x 95mm 3.7/4.0 x 100mm 3.7.4.0 x 110mm 3.7/4.0 x 120mm 3.7.4.0 x 130mm 3.7/4.0 x 140mm 3.7/4.0 x 150mm	Ø6.5 x 40-130mm Ø7.5 x 40-130mm	
Design Feature	Torx drive mechanism Self-drilling and self-tapping	Torx drive mechanism Self-drilling and self-tapping	Same
Prescription vs. OTC	Prescription	Prescription	Same
Sterile vs. Non-Sterile	Non-Sterile	Non-Sterile	Same
Single Use vs. Reusable	Single Use	Single Use	Same

Summary of Non-Clinical Testing

The subject Medline UNITE® IM Fibula Implants do not represent a new worst-case when compared to the previously cleared Medline Cannulated Screws (K130319). Analysis was conducted to further demonstrate substantial equivalence of the Medline UNITE® IM Fibula Implants to the predicate, Medline Cannulated Screws. A summary is present below with more information provided in the applicable sections.

Biocompatibility Testing

The Medline UNITE® IM Fibula Implants are manufactured from titanium alloy conforming to ASTM F136 and ISO 5832-3. The subject device and the predicate device are both manufactured from the identical raw material using the same manufacturing process, therefore, biocompatibility testing was leveraged from the predicate submission to support biocompatibility on the subject device.

Performance Testing (Bench)

The subject device, Medline UNITE® IM Fibula Implants, do not represent a new worst-case when compared to the previously cleared Medline Cannulated Screws (K130319). An engineering analysis was performed to determine that the subject screws do not present a new worst-case for pullout force and torsional yield strength when compared to the predicate. Based on this analysis, the subject device, Medline UNITE® IM Fibula Implants, are substantially equivalent to the predicate, Medline Cannulated Screws.

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

Medline Industries, LP
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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® IM Fibula Implants are substantially equivalent to the predicate device, Medline Cannulated Screws (K130319).