July 22, 2021

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

Re: K211944
Trade/Device Name: Medline UNITE® Digital Fusion Screw System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC
Dated: June 21, 2021
Received: June 23, 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,

For: 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)*
K211944

Device Name
Medline UNITE® Digital Fusion Screw System

Indications for Use *(Describe)*
The Medline UNITE® Digital Fusion 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 including corrective procedures for hammertoe, mallet toe, and claw toe deformities. Screws 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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Three Lakes Drive
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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
Contact Person: Jennifer Mason, Senior Regulatory Affairs Specialist
Phone: 847-643-3652
Email: jamason@medline.com

Summary Preparation Date
June 21, 2021

Type of 510(k) Submission
Special

Device Name / Classification
Trade Name: Medline UNITE® Digital Fusion Screw System
Common Name: Smooth or threaded metallic bone fixation fastener
Classification Name: Screw, Fixation, Bone
Product Code: HWC
Classification Panel: Orthopedics
Regulatory Class: Class II
Regulation Number: 21 CFR 888.3040

Predicate Device
Medline Cannulated Screws (Primary Predicate)
K130319

PRO-TOE VO Hammertoe Implant System
K101165

Device Description
The Medline UNITE® Digital Fusion Screws are manufactured from titanium alloy. The screws are non-sterile and will be offered in a 2.3mm diameter with various thread lengths and overall screw lengths ranging

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from 20mm up to 55mm in 5mm increments. The screws feature low profile headed and headless screws. The screws are self-drilling and self-tapping.

Indications for Use

The Medline UNITE® Digital Fusion 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 including corrective procedures for hammertoe, mallet toe, and claw toe deformities. Screws are intended for single use only.

Summary of Technological Characteristics

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

- Intended use – identical.
- Indications for Use – similar. The indication for use for the Medline UNITE® Digital Fusion Screws are more specific than the predicate but still fall under the same intended use.
- Materials – identical. Both the proposed and predicate device are made from the same material, titanium alloy.
- Sizes – similar. The Medline UNITE Digital Fusion Screws will be offered in a 2.3mm diameter in lengths from 20 – 55mm. The predicate device has diameters ranging from 2.0 to 7.5mm with lengths ranging from 10 – 130mm. The diameters and lengths of the Medline UNITE® Digital Fusion Screws are within the diameters and lengths of the previously cleared Medline Cannulated Screws.

Summary of Non-Clinical Testing

The subject device, Medline UNITE® Digital Fusion Screws, do not represent a new worst-case when compared to the previously cleared Medline Cannulated Screws (K130319). However, analysis was conducted to further demonstrate substantial equivalence of the Medline UNITE® Digital Fusion Screws to the predicate, Medline Cannulated Screws. Based on this analysis, the subject device, Medline UNITE® Digital Fusion Screws, are substantially equivalent to the predicate, Medline Cannulated Screws, in predicted shear failure force (axial pullout force) and torsional yield strength.

Summary of Clinical Testing

Not applicable.

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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® Digital Fusion Screws are as safe and as effective for their intended use as the predicate device, the Medline Cannulated Screw.