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

November 1, 2018

Re: K181820
Trade/Device Name: Medline Unite Mini Plates and Screws
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: HRS, HWC
Dated: July 6, 2018
Received: July 9, 2018

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jesse Muir -S

Digitally signed by Jesse Muir -S
Date: 2018.11.01 11:26:20 -04'00'

For:
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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)*

K181820

Device Name
Medline Unite® Mini Plates and Screws

Indications for Use *(Describe)*

The Medline Unite® Mini Plates and Screws are intended for use in stabilization of fresh fractures, revision procedures, joint fusion and reconstruction of small bones of the hand, feet, wrist, ankles, fingers and toes. The system can be used in both adult and pediatric patients.

Examples include:

- Metatarsal or metacarpal fractures and osteotomies
- Cuboid fractures
- Navicular fractures
- Talar neck fractures
- Jones and avulsion fractures of the 5th metatarsal
- Lesser metatarsal shortening osteotomies (i.e. Weil Osteotomies)
- Phalanges fractures and osteotomies

The Medline Unite® Mini Locking and Non-Locking Screws are indicated for use with the Medline Unite® Plates of the same base material. The Non-Locking Cortical Screws are also indicated for bone reconstruction, osteotomy, arthrodesis, joint fusion, fracture repair, and fracture fixation, appropriate for the size of the device.

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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Submitter / 510(k) Sponsor

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

Registration Number: 1417592

Contact Person

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Senior Regulatory Affairs Specialist
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Summary Preparation Date

September 25, 2018

Type of 510(k) Submission

Traditional

Device Name / Classification

Name of Device: Medline Unite® Mini Plates and Screws
Proprietary Name: Medline Unite® Mini Plates and Screws
Common Name: Plate, Fixation, Bone
Classification Name: Single/multiple component metallic bone fixation appliances and accessories
Product Code: HRS: Plate, Fixation, Bone
HWC: Screw, Fixation Bone
Classification Panel: Orthopedics
Regulatory Class: II
Regulation #: 21 CFR 888.3030

Primary Predicate Device

ORTHOLOC® 2.0/2.4 Plate & ORTHOLOC® 2.0/2.4 Screw
K090692

Predicate Devices

Medline Foot Plates and Screws
K151235

Medline Cannulated Screw
K130319

Reference Device

Monster Screw System
K151418

Device Description

The Medline Unite® Mini Plates and Screws are manufactured from Titanium Alloy. The System includes plates offered in various styles, sizes and options; each contoured for specific anatomy and designed for specific procedures, and 2.0mm, 2.4mm and 2.7mm diameter locking and non-locking screws to be used with the polyaxial locking holes and compression slots included in the plates as well as 4.0mm cannulated screws to be used with the hook plate. The system also includes reusable instrumentation necessary to implant the plates and screws, e.g. drill guides, tissue protectors, and drill bits.

Indications for Use

The Medline Unite® Mini Plates and Screws are intended for use in stabilization of fresh fractures, revision procedures, joint fusion and reconstruction of small bones of the hand, feet, wrist, ankles, fingers and toes. The system can be used in both adult and pediatric patients. Examples include:

- Metatarsal or metacarpal fractures and osteotomies
- Cuboid fractures
- Navicular fractures
- Talar neck fractures
- Jones and avulsion fractures of the 5^{th} metatarsal
- Lesser metatarsal shortening osteotomies (i.e. Weil Osteotomies)
- Phalanges fractures and osteotomies

The Medline Unite® Mini Locking and Non-Locking Screws are indicated for use with the Medline Unite® Mini Plates of the same base material. The Non-Locking Cortical Screws are also indicated for bone reconstruction, osteotomy, arthrodesis, joint fusion, fracture repair, and fracture fixation, appropriate for the size of the device.

Summary of Technological Characteristics

The proposed device is substantially equivalent to the predicate, the Wright Medical ORTHOLOC®

Both devices have the same intended use, same materials (titanium alloy), similar design features and both systems are provided non-sterile.

Both the Medline Unite® Mini Plates and the predicate plates feature locking and compression slots and polyaxial locking up to 15 degrees. Both systems feature locking and non-locking screws made from the same material, titanium alloy.

Summary of Non-Clinical Testing

Testing was conducted to demonstrate substantial equivalence of the Medline Unite® Mini Plates and Screws to the predicate, Wright Medical ORTHOLOC® 2.0/2.4 Plates and Screws.

Plates

The following tests were performed in accordance with ASTM F382-17 to demonstrate substantial equivalence between the proposed Medline Unite® Mini Plates and the predicate Wright Medical ORTHOLOC® 2.0/2.4 Plates.

Single Cycle 4-Point Bend Testing

Single cycle 4-point bend testing was conducted per ASTM F382. The purpose of this test was to ensure that the bending stiffness of the proposed Medline Unite® Mini Plates was equivalent to the bending stiffness of the predicate Wright Medical Plates. The results from single cycle 4-point bend test demonstrate that the Medline Unite® Mini Plates and the predicate Wright Medical ORTHOLOC® 2.0/2.4 plates are substantially equivalent in 4-point static bend testing.

Screws

The following tests were performed in accordance with ASTM F543-17 to demonstrate substantial equivalence between the proposed Medline Unite® Mini Screws and the predicate Wright Medical ORTHOLOC®2.0/2.4 Screws.

Static Axial Pullout Testing

Static axial pullout testing was conducted per ASTM F543-17. The purpose of this test was to ensure that the axial pullout strength of the proposed Medline Unite® Mini Locking Screws and Non-Locking Cortical Screws were equivalent to the pullout strength of the predicate Wright Medical ORTHOLOC®2.4/2.4 Locking and Non-Locking Screws. The results from the axial pullout test demonstrate that the Medline Locking and Non-locking Screws and the predicate Wright Medical ORTHOLOC® 2.0/2.4 Locking and Non-locking Screws are equivalent in axial pullout.

Static Torsion Testing

Static torsion testing was conducted per ASTM F543-17. The purpose of this test was to ensure that the torsional strength of the proposed Medline Locking and Non-Locking Screws was equivalent to the torsional strength of the predicate Wright Medical ORTHOLOC® Locking and Non-Locking Screws. The results from the static torsional testing show that the Medline Locking and Non-locking Screws and the predicate Wright Medical ORTHOLOC® 2.0/2.4 Locking and Non-locking Screws are equivalent in torsional strength.

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® Mini Plates and Screws are substantially equivalent to the predicate device, the ORTHOLOC® 2.0/2.4 Plate System K090692.