June 17, 2020

Medline Industries, Inc.
Jennifer Mason
Senior Regulatory Affairs Specialist
Three Lakes Drive
Northfield, Illinois 60030

Re: K201319
Trade/Device Name: Medline UNITE Jones Fracture Screw System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC, HTN
Dated: May 15, 2020
Received: May 18, 2020

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)*

K201319

Device Name

Medline UNITE Jones Fracture Screw System

Indications for Use *(Describe)*

The Medline UNITE® Jones Fracture Screws are indicated for use in bone reconstruction, osteotomies, arthrodesis, joint fusion and repair and fixation of mal-unions, non-unions, acute fractures, avulsion fractures, and repetitive stress fractures for bones appropriate for the size of the device including the fifth metatarsal (Jones fracture). 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.

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K201319
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
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Summary Preparation Date
June 16, 2020

Type of 510(k) Submission
Special

Device Name / Classification
Name of Device: Medline UNITE® Jones Fracture Screw System
Proprietary Name: Medline UNITE® Jones Fracture Screw System
Common Name: Screw, Fixation, Bone
Classification Name: Smooth or threaded metallic bone fixation fastener
Product Code: HWC, HTN
Classification Panel: Orthopedics
Regulatory Class: II
Regulation #: 21 CFR 888.3040 (Primary) and 21 CFR 888.3030

Predicate Device
K130319 – Medline Cannulated Screw (Primary)
K183026 – Wright Jones Fracture System

Device Description

The Medline UNITE® Jones Fracture Screws are manufactured from titanium alloy. The screws are offered in various diameters ranging from 4.5mm up to 6.0mm and overall lengths ranging from 34mm up to 65mm with consistent thread lengths.

Indications for Use

The Medline UNITE® Jones Fracture Screws are indicated for use in bone reconstruction, osteotomies, arthrodesis, joint fusion and repair and fixation of mal-unions, non-unions, acute fractures, avulsion fractures, and repetitive stress fractures for bones appropriate for the size of the device including the fifth metatarsal (Jones fracture). Screws are intended for single use only.

The indications for use differ from the primary predicate because they contain more specific indications for use that are consistent with other screws cleared under 21 CFR 888.3040. These differences are not critical to the intended therapeutic affect because the more specific indications fall within the intended use of fracture fixation.

Summary of Technological Characteristics

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

- Intended use – identical.
- Indications for Use – similar. The indications for use for the Jones Fracture Screws are more specific than the predicate but still fall under the same intended use of fracture fixation.
- Materials – identical. Both the subject device and the predicate device are made from titanium alloy per ASTM F136.
- Geometry and Size – similar. The subject device will be offered in diameters of 4.5mm, 5.5mm and 6.0mm with lengths ranging from 34mm – 65mm. These diameters and lengths are within the diameters and lengths of the predicate device which ranges from 2.0mm to 7.5mm in diameter and 10mm to 130mm in length.
- Design Feature – similar. The Jones Fracture Screws are solid core screws, whereas, the predicate screws are cannulated. Both the subject device and the predicate device feature a torx drive mechanism. The predicate device is self-drilling and self-tapping. The subject device is only self-drilling to reduce the risk of penetrating the far cortex of the 5th metatarsal which would lead to bi-

cortical fixation. Intramedullary fixation rather than bi-cortical fixation is typically preferred in 5th metatarsal fracture fixation.

Summary of Non-Clinical Testing

ASTM F543 testing (insertion torque testing, torsional strength testing, and axial pullout strength testing) and engineering analysis were used to compare screw mechanical performance, fixation performance and usability.

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® Jones Fracture Screws are substantially equivalent to the predicate device, the Medline Cannulated Screw.