DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

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

August 18, 2017

Re: K170782
Trade/Device Name: Medline UNITE® Snap-Off Screws
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC
Dated: August 2, 2017
Received: August 3, 2017

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Mark N. Melkerson -S

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K170782

Device Name
Medline UNITE® Snap-Off Screws

Indications for Use *(Describe)*
The Medline UNITE® Snap-Off 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.

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

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
August 1, 2017

Type of 510(k) Submission
Special

Device Name / Classification
Name of Device: Medline UNITE® Snap-Off Screws
Proprietary Name: Medline UNITE® Snap-Off Screws
Common Name: Screw, Fixation, Bone
Classification Name: Smooth or threaded metallic bone fixation fastener
Product Code: HWC
Classification Panel: Orthopedics
Regulatory Class: II
Regulation #: 21 CFR 888.3040

Predicate Device
Medline Cannulated Screw
K130319

Additional Predicate Device
Wright Medical CHARLOTTE™ Snap-Off Screw
K133713

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

Device Description

The Medline UNITE® Snap-Off Screws are manufactured from titanium alloy. The screws include a groove between the head and the drive mechanism that is intended to snap off the drive mechanism below the surface of the head of the screw. The screws are offered in various diameters, lengths, and thread lengths.

Indications for Use

The Medline UNITE® Snap-Off 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.

Summary of Technological Characteristics

The proposed modified device is substantially equivalent to the predicate, the Medline Cannulated Screw. Both devices have the same intended use, same indications for use, same materials (Ti-6AL-4V), are provided non-sterile and have similar design features. The predicate Snap-Off Screws are offered in 2.0 and 2.7mm diameters in lengths from 11-21mm, which is within the previously cleared range for the Medline Cannulated Screws including 2.0-7.5mm diameters in lengths from 10-130mm.

Both the subject and the predicate screws are partially threaded, self-drilling and self-tapping. In addition, both the subject and predicate screw incorporate a drive feature; for the subject Snap-Off Screw the drive feature is attached to the screw and breaks away during insertion and ther is a three pronged external drive feature used for finally seating the screw, the predicate Medline Cannulated Screws incorporate various size torx drives.

Summary of Non-Clinical Testing

The subject screw does not present a new worst-case when compared to the predicate screw in torsional or pullout 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® Snap-Off Screws are safe, effective and substantially equivalent to the predicate, the Medline Cannulated Screw.