510(k) Summary

MAY 3 1 2013

Summary Preparation Date

May 17, 2013

Submitter / 510(k) Sponsor

Medline Industries, Inc.
One Medline Place
Mundelein, IL 60060

Contact Person

Matt Clausen
Sr. Regulatory Affairs Specialist
Phone: 847-643-4785
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Device Name / Classification

Device Name: Orthopedic Cannulated Screw
Proprietary Name: Medline Cannulated Screw
Common Name: Bone Screw
Classification Name: Screw, Fixation, Bone (21 CFR 888.3040, product code – HWC)

Predicate Device (primary)

Wright Compression Screws (Wright Medical), K082320

Device Description

The Medline Cannulated Screws are manufactured from titanium alloy or stainless steel. The screws are offered in various diameters, lengths, and thread lengths. Both headed and headless screw options are available as well as optional washers for the headed screws. A comparison of the materials and design features of the subject and predicate screws reflects substantial equivalence. The Medline Cannulated Screw sizes are within the currently marketed sizes, diameter and length, of the identified predicate devices.

Indications for Use

The 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.

Summary of Technological Characteristics

Information within this Premarket Notification demonstrates that there are no significant differences in technological characteristics between Medline's Cannulated Screws and the cited predicate devices.

Summary of Non-Clinical Testing

The safety and effectiveness of Medline's Cannulated Screws is adequately supported by the substantial equivalence information, materials information, and analysis data provided within this Premarket Notification. Functional performance testing of the Medline Cannulated Screws demonstrated device effectiveness in accordance with relevant ASTM F382 and F543 test methods.

Summary of Clinical Testing

N/A

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 Cannulated Screw is safe, effective and substantially equivalent as described herein.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 31, 2013

Medline Industries, Incorporated
% Mr. Matt Clausen
Sr. Regulatory Affairs Specialist
One Medline Place
Mundelein, Illinois 60060

Re: K130319
Trade/Device Name: Medline Cannulated Screws
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC
Dated: March 6, 2013
Received: March 7, 2013

Dear Mr. Clausen:

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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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 yours,

For Erin I. Keith

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use

510(k) Number (if known): K130319 (pg 1/1)

Device Name: Medline Cannulated Screws

Indications for Use:

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth L. Frank -S

Division of Orthopedic Devices