



Food and Drug Administration
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Silver Spring, MD 20993-0002

Smith & Nephew, Inc.
Ms. Samantha Staubach
Regulatory Affairs Specialist
1450 East Brooks Road
Memphis, TN 38116

August 23, 2017

Re: K172262

Trade/Device Name: EVOS Small Fragment Plating System

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 26, 2017

Received: July 27, 2017

Dear Ms. Staubach:

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 (DICE) 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 (DICE) 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,

Katherine D. Kavlock

-S

for

Mark N. Melkerson

Director

Division of Orthopedic Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K172262

Device Name

EVOS Small Fragment Plating System

Indications for Use (Describe)

The EVOS Small Fragment Plating System is indicated for adult and pediatric patients, as well as patients with osteopenic bone. It is indicated for fixation of small and long bone fractures, including, but not limited to, those of the tibia, fibula, femur, humerus, ulna, radius, pelvis, acetabulum, metacarpals, metatarsals, and clavicle.

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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Submitted by: Smith & Nephew, Inc.
Orthopaedic Division
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Memphis, Tennessee 38116

Date of Summary: August 18, 2017
~
Samantha Staubach
Regulatory Affairs Specialist
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Name of Device: EVOS Small Fragment Plating System

Common Name: Bone Screws

Device Classification Name and Reference: 21CFR 888.3030 Single/multiple component metallic bone fixation appliances and accessories
21 CFR 888.3040 Smooth or threaded metallic bone fixation fastener

Device Class: Class II

Panel Code: Orthopaedics/87

Product Code: HRS/HWC

Predicates

Manufacturer	Description	Submission Number	Clearance Date
Smith & Nephew, Inc.	Smith & Nephew, Inc. EVOS Small Fragment Plating System	K162078	November 18, 2016

Device Description

The subject of this special premarket notification are minor modifications to the 3.5mm non-locking cortex screws and 4.7mm non-locking osteopenia screws (fully and partially threaded) previously cleared for market via Traditional 510(k), K162078. Design modifications described in this submission include minor updates to the tip of the cortex screw design and an increase in the screw head diameter for both the cortex and osteopenia screws.

The subject EVOS Small Fragment non-locking screws are intended to be used with existing Smith & Nephew implants and instruments that have been previously cleared for market for use with the EVOS Small Fragment Plating System.

Indications for Use

The EVOS Small Fragment Plating System is indicated for adult and pediatric patients, as well as patients with osteopenic bone. It is indicated for fixation of small and long bone fractures, including, but not limited to, those of the tibia, fibula, femur, humerus, ulna, radius, pelvis, acetabulum, metacarpals, metatarsals, and clavicle.

Technological Characteristics

The subject devices are very similar to existing Smith & Nephew Plating System 3.5mm non-locking cortex screws and 4.7mm non-locking osteopenia screws cleared via K162078. The minor modifications to the tip of the cortex screw and the head of the cortex and osteopenia screws are not expected to impact device safety or effectiveness, as demonstrated through mechanical testing. Device comparisons described in this premarket notification demonstrated that the proposed devices are identical to the predicate EVOS Small Fragment Plating System non-locking screws with respect to intended use, indications, materials, methods of manufacture, sterility, and packaging.

Summary of Pre-Clinical Testing

- Screw insertion testing – Insertion testing was conducted for the cortex screws with modified tips and was compared to the existing EVOS design. Results of the testing demonstrated that screws manufactured with the modified tip performed similar or superior to the existing EVOS screw design.
- Maximum stripping torque testing – EVOS screws with modified screw head diameters were compared against the existing EVOS screw design. Results of the testing demonstrated that the proposed head design modification met the acceptance criteria in that they were significantly different compared to the current EVOS screw design (increase in maximum stripping torque).
- Engineering rationale – Pyrogen testing was previously conducted for EVOS screws to support clearance of K162078. Existing results for the EVOS implants, as well as other implants cleaned using the same cleaning system that are considered more worst-case in terms of features, were reviewed and it was determined that the subject devices do not represent a new worst-case device.

Conclusion

This Special 510(k) premarket notification is being submitted to request clearance for the modified non-locking screws intended to be used with the EVOS Small Fragment Plating System. Based on similarities to the predicate components and a review of the mechanical testing performed, the subject modified screws are substantially equivalent to the predicate screws cleared via K162078.