MAY 07 2014

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Submitted by:	Smith & Nephew, Inc. Orthopaedic Division 1450 East Brooks Road Memphis, Tennessee 38116
Date of Summary:	May 2, 2014
Contact Person and Address:	Samantha Staubach Regulatory Affairs Specialist I T 901-399-6132 F 901-566-7596
Name of Device:	EVOS Mini-Fragment Plating System
Common Name:	Bone Plates, Screws and Washers
Device Classification Name and Reference:	21 CFR 888.3030 Single/multiple component metallic bone fixation appliances and accessories Class II 21 CFR 888.3040 Smooth or threaded metallic bone fixation fastener Class II
Panel Code:	Orthopedics/87
Product Code:	HRS/HTN/HWC

Device Description

The subject **EVOS Mini-Fragment Plating System** is a modification to a subset of the devices previously cleared Smith & Nephew Variable-Angle Locking Mini-Fragment Plating System (K132886). It is an internal fixation plating system comprised of assorted implantable, small utility *"flat" locking bone plates* and compatible *locking* and *non-locking bone screws* and *washers* to be used on various small bones and fragments. Plates consist of groups of devices with a flat cross-section where the number of holes in plates will range from 4 through 20. All described implant devices are manufactured from implant-grade 316L Stainless Steel material and will be available in a sterile or non-sterile packaged condition.

Intended Use

Bone plates and bone screws from the EVOS Mini-Fragment Plating System are intended for use in internal fixation of small bones and fragments and as non-load bearing stabilization and fixation of bone fragments.

Indications for Use

The Smith & Nephew Variable-Angle Locking Mini-Fragment Plating System is indicated for adolescent (12-18 years) and transitional adolescent (18-21 years) subpopulations and adults, as well as patients with osteopenic bone. The Smith & Nephew Variable-Angle Locking Mini-

Fragment Plating System is indicated for fracture fixation, arthrodesis, reconstruction, replantation or reduction of small bones and fragments. This system is also indicated for non-load bearing stabilization and reduction of bone fragments in long bones.

Components in the Smith & Nephew Variable-Angle Locking Mini-Fragment Plating System are for single use only.

Technological Characteristics

Device comparisons described in this premarket notification demonstrate that the proposed bone plates and bone screws are substantially equivalent to the legally marketed predicate devices (listed below in *Table 1*) with regard to intended use, indications for use, and performance characteristics.

Substantial Equivalence Information

When compared to the predicate devices listed below, substantial equivalence is based on *similar* function, intended use, indications for use, and overall design to the devices listed in the table below.

Table 1: Substantially Equivalent Predicates to the EVOS Mini-Fragment Plating System

Manufacturer	Description	Submission Number	Clearance Date
Smith & Nephew, Inc.	Variable-Angle Locking Mini-Fragment Plating System	K132886	02-04-2014
Smith & Nephew, Inc.	Plate and Screw Instruments	K123055	01-25-2013
Smith & Nephew, Inc.	VLP FOOT Plating, Screw System and Accessories	K090675	06-04-2009

Summary of Pre-Clinical Testing

To further support a determination of substantial equivalence, non-clinical bench (mechanical) testing was conducted to support the proposed bone plates and bone screws. Test results demonstrated that the proposed devices are substantially equivalent to one or more of the previously cleared predicate devices described above. The specific types of non-clinical testing conducted are listed below.

- *Finite Element Analysis (FEA)* was conducted on all proposed bone plates to predict the worst-case plate to be used in subsequent non-clinical bench (mechanical) testing.
- *Four-point bend fatigue testing* was conducted on the worst-case bone plates identified through FEA. Results of testing concluded that, when compared to

predicates tested at the same bending moment, the number of log cycles to failure met the acceptance criteria in that they were found to be non-inferior to the number of log cycles to failure achieved by the predicates.

- *Four-point bend fatigue testing* was also performed on the proposed 2.0mm, 2.4mm, and 2.7mm bone screws. Results of the testing concluded that, compared to the predicates and when tested at the same bending moment, the proposed bone screws met the acceptance criteria in that they were found to be non-inferior to the number of log cycles to failure achieved by the predicates.
- *Torque-to-failure testing* of the proposed 2.0mm, 2.4mm, and 2.7mm cortex screws and 4.0mm osteopenia screws was conducted. Results concluded that the average values for torsional strength of the proposed devices met the acceptance criteria in that they were non-inferior to the predicates and non-inferior to the minimum values cited in ASTM F543.

Conclusion

As previously noted, this Special 510(k) Premarket Notification is being submitted to request clearance for the EVOS Mini-Fragment Plating System. Based on the similarities to the predicate components and a review of the mechanical testing performed, the devices are substantially equivalent to the predicate plating systems listed above in *Table 1*.

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 7, 2014

Smith & Nephew, Incorporated
Ms. Samantha Staubach
Regulatory Affairs Specialist I
1450 Brooks Road
Memphis, Tennessee 38116

Re: K140814
Trade/Device Name: EVOS Mini-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, HTN, HWC
Dated: April 10, 2014
Received: April 11, 2014

Dear Ms. Samantha 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 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 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 yours,

Lori A. Wiggins

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

Enclosure

Premarket Notification
Indications for Use Statement

510(k) Number (if known): K140814

Device Name: EVOS Mini-Fragment Plating System

Indications for Use:

The Smith & Nephew Variable-Angle Locking Mini-Fragment Plating System is indicated for adolescent (12-18 years) and transitional adolescent (18-21 years) subpopulations and adults, as well as patients with osteopenic bone. The Smith & Nephew Variable-Angle Locking Mini-Fragment Plating System is indicated for fracture fixation, arthrodesis, reconstruction, replantation or reduction of small bones and fragments. This system is also indicated for non-load bearing stabilization and reduction of bone fragments in long bones.

Bone plates and bone screws from the Smith & Nephew Variable-Angle Locking Mini-Fragment Plating System are for single use only.

Prescription Use __X__ AND/OR Over-the-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of Center for Devices and Radiological Health (CDRH)

Casey Hanley -S

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K140814