



Food and Drug Administration
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Smith & Nephew, Incorporated
Ms. Samantha Staubach
Regulatory Affairs Specialist I
1450 East Brooks Road
Memphis, Tennessee 38116

November 12, 2015

Re: K152976

Trade/Device Name: VLP Mini-Mod Talus Plates

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: October 6, 2015

Received: October 8, 2015

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 Parts 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,

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

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

Indications for Use

510(k) Number (if known)
K152976

Device Name
VLP Mini-Mod Talus Plates

Indications for Use (Describe)

The VLP Mini-Mod Talus Plates can be used in adolescent (12-18 years) and transitional adolescent (18-21 years) subpopulations and adults, as well as patients with osteopenic bone. The VLP Mini-Mod Talus Plates are indicated for fracture fixation, reconstruction or arthrodesis of small bones, including those in the forefoot, midfoot and hindfoot.

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
 1450 East Brooks Road
 Memphis, Tennessee 38116

Date of Summary: November 10, 2015

Contact Person and Address: Samantha Staubach
 Regulatory Affairs Specialist I
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Name of Device: VLP Mini-Mod Talus Plates

Common Name: Bone plates

Device Classification Name and Reference: 21 CFR 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.	VLP FOOT Plating System and PERI-LOC Ankle Fusion Plating System – Locking Bone Plates and Screws (Primary Predicate)	K110670	7/12/11
Smith & Nephew, Inc.	Smith & Nephew Variable-Angle Locking Mini-Fragment Plating System	K132886	2/4/14
Synthes (USA)	Synthes (USA) 2.4/2.7mm Locking Foot Module	K071264	7/9/2007
Smith & Nephew, Inc.	Smith & Nephew Bone Plate System (Bone Plates, Bone Screws, and Accessories)	K993106	12/9/1999

Device Description

The subject premarket notification describes talus plate line additions to the VLP Mini-Mod Small Bone Plating System. Subject plates consist of several varieties of medial and lateral talus plates in left and right designs. All described implant devices are manufactured from implant-grade titanium alloy material (Ti-6Al-4V) and designed for single-use. They will be provided in a sterile-packaged option and will be sterilized via Gamma irradiation.

Indications for Use

The VLP Mini-Mod Talus Plates can be used in adolescent (12-18 years) and transitional adolescent (18-21 years) subpopulations and adults, as well as patients with osteopenic

bone. The VLP Mini-Mod Talus Plates are indicated for fracture fixation, reconstruction or arthrodesis of small bones, including those in the forefoot, midfoot and hindfoot.

Technological Characteristics

Device comparisons described in this premarket notification demonstrated that the proposed talus plates are substantially equivalent to the legally marketed primary predicate devices cleared in K110670 with regard to intended use, indications for use, and performance characteristics.

The subject VLP Mini-Mod Talus Plates feature characteristics very similar to the VLP FOOT Plating System talus plates cleared via K110670 with the primary differences being the material selection, the addition of device-specific bone template instrumentation and different packaging configuration. The subject plates feature identical indications for use and intended use as the talus plates offered in K110670 and the same plate design options from K110670 will be available with the VLP Mini-Mod system.

Summary of Pre-Clinical Testing

- *Finite element analysis (FEA)* was conducted on the proposed talus plate designs to evaluate the effect of the material change from Stainless Steel to Ti-6Al-4V. This testing was used to determine the worst case plate as well as the high stress region of the plates.
- *Four-point bend fatigue testing* was conducted on worst-case examples of the proposed bone plates, as identified through FEA testing. Results of the testing concluded that the number of log cycles to failure achieved by the proposed bone plates met the acceptance criteria in that they were found to be non-inferior to the fatigue log cycles to failure of a previously cleared predicate.
- *Engineering analysis* based on the device geometry and nominal material properties.
- *Packaging testing* consisting of post-sterilization visual inspection, a package challenge test, post package challenge test visual inspection, and seal integrity bubble emission testing showed that the product will not be damaged during shipping and will maintain sterility post-shipment.

Conclusion

This Special 510(k) premarket notification is being submitted to request clearance for the VLP Mini-Mod Talus Plates. Based on the similarities to the predicate components and a review of the mechanical testing performed, the devices are substantially equivalent to the predicate talus plates.