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

December 21, 2016

Smith & Nephew, Inc.
Samantha Staubach
Regulatory Affairs Specialist
1450 Brooks Rd
Memphis, Tennessee 38116

Re: K163086
Trade/Device Name: VLP MINI-MOD 2.0 mm Column 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
Dated: November 2, 2016
Received: November 3, 2016

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 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,

Vincent J. Devlin -S

for

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)*
K163086

Device Name
VLP MINI-MOD 2.0mm Column Plates

Indications for Use *(Describe)*
The VLP MINI-MOD Small Bone Plating System and VLP MINI-MOD Talus Plates are indicated for adolescent (12–18 years) and transitional adolescent (18–21 years) subpopulations and adults, as well as patients with osteopenic bone.

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

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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We are smith&nephew

Submitted by:	Smith & Nephew, Inc. Orthopaedic Division 1450 East Brooks Road Memphis, Tennessee 38116
Date of Summary:	December 21, 2016
Contact Person and Address:	Samantha Staubach Regulatory Affairs Specialist T 901-399-6132 F 901-566-7596
Name of Device:	VLP MINI-MOD 2.0mm Column Plates
Common Name:	Bone plates
Device Classification Name and Reference:	21CFR 888.3030 Single/multiple component metallic bone fixation appliances and accessories
Device Class:	Class II
Panel Code:	Orthopaedics/87
Product Code:	HRS

Predicates

Table 5-1: Substantially equivalent predicates

Manufacturer	Description	Submission Number	Clearance Date
Smith & Nephew, Inc.	Smith & Nephew Variable-Angle Locking Mini-Fragment Plating System (Primary Predicate)	K132886	2/4/2014
Smith & Nephew, Inc.	Smith & Nephew Bone Plate System	K993106	12/9/1999

Device Description

The subject VLP MINI-MOD 2.0mm Column Plates are line addition plates to the VLP MINI-MOD Small Bone Plating System. The VLP MINI-MOD Small Bone Plating System was initially cleared for market via K132886 as the Smith & Nephew Variable-Angle Locking Mini-Fragment Plating System. The proposed plates are intended to be used with the 2.0mm Locking and Cortex screws previously cleared via K132886.

Indications for Use

The VLP MINI-MOD Small Bone Plating System and VLP MINI-MOD Talus Plates are indicated for adolescent (12–18 years) and transitional adolescent (18–21 years) subpopulations and adults, as well as patients with osteopenic bone.

The VLP MINI-MOD Small Bone Plating System is indicated for fracture fixation, arthrodesis, reconstruction, replantation or reduction of small bones and small bone fragments. This

system is also indicated for non-load bearing stabilization and reduction of bone fragments in long bones.

Technological Characteristics

Device comparisons described in this premarket notification demonstrated that the proposed VLP MINI-MOD 2.0mm Column Plate is substantially equivalent to the legally marketed predicate devices described in *Table 5-1* with regard to intended use, indications for use, and performance characteristics.

Summary of Pre-Clinical Testing

- *Finite element analysis (FEA)* was conducted on the proposed VLP MINI-MOD 2.0mm Column Plate to determine if it represented a new worst case compared against the existing MINI-MOD plates cleared via K132886. The subject plate did not represent a new worst case plate design.
- An engineering rationale was used to leverage the four-point bend fatigue testing that was previously conducted on the worst-case plate of the VLP MINI-MOD product family cleared via K132886. 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 when tested at the same bending moment. Due to the fact that the subject plate did not represent a new worst case, the testing was also applicable to the subject line addition plate.
- Bacterial endotoxin testing was completed and met the acceptable endotoxin limits as stated in the FDA Guidance , "Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile," "Pyrogen and Endotoxins Testing: Questions and Answers," and ANSI/AAMI ST72.

Conclusion

This Traditional 510(k) premarket notification is being submitted to required clearance for the line addition VLP MINI-MOD 2.0mm Column Plate. Based on similarities to the predicate component and a review of the engineering rationale/mechanical testing previously conducted, the devices are substantially equivalent to the predicates described in *Table 5-1.*