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

November 15, 2016

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

Re: K161665
Trade/Device Name: VLP Wrist Fracture 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: October 28, 2016
Received: October 31, 2016

Dear 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" (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,

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

Indications for Use

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

510(k) Number *(if known)*

K161665

Device Name
VLP Wrist Fracture System

Indications for Use *(Describe)*
The VLP Wrist Fracture System Radial Plates are indicated for fixation of fractures, malunions, and osteotomies involving the radius.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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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:	October 28, 2016
Contact Person and Address:	Samantha Staubach Regulatory Affairs Specialist T 901-399-6132 F 901-566-7596
Name of Device:	VLP Wrist Fracture System
Common Name:	Bones Plates and Screws
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

Table 1: Substantially Equivalent Predicates to the VLP Wrist Fracture System

Manufacturer	Description	Submission Number	Clearance Date
Smith & Nephew, Inc.	**Smith & Nephew, Inc. D-RAD SMARTPACK (primary predicate)**	**K132296**	**January 7, 2014**
Smith & Nephew, Inc.	Smith & Nephew Bone Plate System	K993106	December 9, 1999
Synthes (USA)	Synthes 3.5mm Cortex Screws	K043185	February 3, 2005
Smith & Nephew, Inc.	PERI-LOC Periarticular Locked Plating System Hexalobular Bone Screws	K082516	September 17, 2008
Smith & Nephew, Inc.	PERI-LOC Bone Plating and Screw System	K083032	January 7, 2009
Biomet Trauma	Modified Distal Radius Plating System	K133939	April 1, 2014

Device Description

The VLP Wrist Fracture System is a radial plating system comprised of plates, screws, and device specific instrumentation. Plates, screws, and locking pegs are provided in sterile packaging. Volar plate design options are offered in 3 hole, 4 hole, 5 hole, and 10 hole plate configurations, with both standard and wide sizes available for all sizes except the 10 hole plate. The 10 hole plate is available in standard size only. All plate designs are available in left and right configurations. 1.8mm Locking Pegs are available in lengths ranging from 10mm to

30 mm and 3.5mm Cortex and Locking Screws are available in lengths ranging from 10mm to 30mm. The system uses existing Smith & Nephew 2.4mm locking and cortex screws.

Indications for Use
The VLP Wrist Fracture System Radial Plates are indicated for fixation of fractures, malunions, and osteotomies involving the radius.

Technological Characteristics
The proposed radial plates are similar to the predicates described in *Table 1*. Device comparisons described in this premarket notification demonstrated that the proposed bone plates and bone screws are substantially equivalent to the legally marketed predicate devices listed in *Table 1* with regard to intended use, indications for use, materials, and performance characteristics. The subject plates feature similarities in design to the primary predicate, with the major difference being the increased product offering. To accommodate for the size differences in the screws compared to the primary predicate, mechanical testing was conducted on the subject screw and an engineering rationale was leveraged based on similar design features to existing Smith & Nephew screw designs.

Summary of Pre-Clinical Testing

- Finite element analysis (FEA) was conducted on the proposed line addition plate designs to evaluate the proposed designs against the existing worst case plate design from K132296. Results of the testing determined that the proposed line addition plates did not represent a new worst-case when compared against the existing designs.
- Existing mechanical testing for four-point bend fatigue was leveraged based on the fact that the 4 Hole Wide Plate design previously cleared via K132296 is also being offered in the subject system with minor modifications. As described above, FEA did not result in a new worst-case plate design compared against the existing worst-case, the 4 Hole Wide Plate cleared via K132296.
- Torque-to-failure testing was conducted on the subject 3.5mm locking screws. The screws met the acceptance criteria by achieving an ultimate torsional strength greater than the minimum value outlined in ASTM F543.
- An engineering rationale was leveraged in lieu of pullout testing for the proposed 3.5mm screws. The dimensions critical to screw behavior during pullout testing were compared between the subject screws and an existing Smith & Nephew predicate screw and the dimensions were identical. As such, it was determined that completion of pullout testing was not necessary.
- 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

As previously noted, this Traditional 510(k) Premarket Notification is being submitted to request clearance for the VLP Wrist Fracture System. Based on the similarities to the predicate devices and a review of the mechanical testing performed and leveraged, the devices are substantially equivalent to the plating systems described in *Table 1*.