December 22, 2017

Smith & Nephew
Allison Chan
Regulatory Affairs Specialist II
1450 E Brooks Road
Memphis, Tennessee 38116

Re: K172785
Trade/Device Name: CONQUEST FN
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: JDO, KTT
Dated: December 11, 2017
Received: December 12, 2017

Dear Ms. Chan:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

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)*

K172785

Device Name
CONQUEST FN

Indications for Use *(Describe)*
The Smith & Nephew Conquest FN is indicated for displaced and undisplaced intracapsular femoral neck fractures.

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. Advance Surgical Devices Division 1450 East Brooks Road Memphis, Tennessee 38116
Date of Summary:	December 11,2017
Contact Person and Address:	Allison Chan Regulatory Affairs Specialist II T (901) 399-1098 F (901) 566-7022
Name of Device:	CONQUEST FN
Common Name:	Internal Fracture Fixation Device
Device Classification Name and Reference:	21 CFR 888.3030 Single/multiple component metallic bone fixation appliances and accessories Class II
Panel Code:	Orthopedics/87
Product Code:	JDO,KTT

Device Description

The CONQUEST FN system is comprised of contoured locking bone plates and compatible locking and non-locking bone screws. The subject premarket notification describes additional lengths of the proximal locking compression screws to the Smith & Nephew CONQUEST FN system. The subject devices are manufactured from the same implant-grade stainless steel (316L) and designed for single-use. They will be provided in a sterile packaged option and will be sterilized via Gamma irradiation.

Intended Use

The Smith & Nephew CONQUEST FN is indicated for displaced and undisplaced intracapsular femoral neck fractures.

Comparison to Technological Characteristics with Predicate Device

Device comparisons described in this premarket notification demonstrated that the proposed CONQUEST FN proximal locking compression screws are substantially equivalent to the legally marketed predicate devices listed below with regard to intended use, indications for use, and performance characteristics.

The subject proximal locking compression screws features characteristics very similar to the CONQUEST FN system proximal locking compression screws cleared via K152686, with the primary differences being shorter overall screw length and minor thread length differences. All other design aspects, indications for use, intended use, material and fundamental scientific technology remain the same as those in K152686.

Summary of Pre-Clinical Testing

- *OR-17-111: Axial Pullout Strength Evaluation* was conducted on the CONQUEST FN proximal locking compression screws as compared to the Targon FN Titanium System. Results of the test concluded that the CONQUEST FN Locking Screws met the acceptance criteria and exhibited similar or superior axial pullout strength compared to the predicate device.
- *OR-17-164: Axial Pullout Strength Evaluation* was conducted on the CONQUEST FN proximal locking compression screws as compared to the cannulated screws. Results of the test concluded that the CONQUEST FN proximal locking screws met the acceptance criteria and exhibited similar or superior axial pullout strength as compared to the predicate device.

Bacterial endotoxin testing was completed and met the acceptable endotoxin limits as stated in FDA Guidance ,"Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile," "Pyrogen and Endotoxin Testing: Questions and Answers," and ANSI/AAMI ST72.

Substantial Equivalence Information

The substantial equivalence of the CONQUEST FN proximal locking compression screws is based on its similarities in indications for use, design features, sterilization methods, and materials to the predicate systems listed in the following table.

Table 5.1: Substantially Equivalent Predicates to CONQUEST FN Proximal Locking Compression Screws

Manufacturer	Description	Submission Number	Clearance Date
Smith & Nephew	CONQUEST FN***(Primary Predicate)***	K152686	3/17/2016
Smith & Nephew	Cannulated Screws and Washers	K111994	10/11/2011
Aesculap Implant Systems, LLC	Targon FN System	K102057	12/21/2010
FxDevices	POGO Screw	K080649	11/25/2008