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

March 17, 2016

Smith & Nephew, Incorporated
Bradley Heil
Regulatory Affairs Manager
1450 East Brooks Road
Memphis, Tennessee 38116

Re: K152686
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: February 16, 2016
Received: February 18, 2016

Dear Mr. Heil:

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

Indications for Use

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

510(k) Number *(if known)*

K152686

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

We are smith&nephew

Submitted by:	Smith & Nephew, Inc. Advance Surgical Devices Division 1450 East Brooks Road Memphis, Tennessee 38116
Date of Summary:	March 15, 2016
Contact Person and Address:	Bradley Heil Regulatory Affairs Manager T (901) 399-6339 F (901) 566-7831
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 subject premarket notification describes the Smith & Nephew CONQUEST FN. The subject internal fixation plating system is comprised of contoured locking bone plates and compatible locking and non-locking bone screws. All described implant devices are manufactured from 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

CONQUEST FN is intended for use in internal fixation of femoral neck fractures

Indications for Use

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

Technological Characteristics

Device comparisons described in this premarket notification demonstrated that the proposed CONQUEST FN implants are substantially equivalent to the legally marketed predicate devices listed below with regard to intended use, indications for use, and performance characteristics. The subject CONQUEST FN features characteristics very similar to the Targon FN cleared via K102057, with the primary differences being material changes and the utilization of POGO Screw technology (K080649). To accommodate for differences between the subject device and the predicate cleared via K102057, mechanical testing was conducted to compare the two devices.

Substantial Equivalence Information

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

Table 1: Substantially Equivalent Predicates to CONQUEST FN

Manufacturer	Description	Submission Number	Clearance Date
Aesculap Implant Systems, LLC	Targon FN System ***(Primary Predicate)***	K102057	12/21/10
FxDevices	POGO Screw	K080649	11/25/08
Smith & Nephew	Smith & Nephew Cannulated Screws and Washers	K111994	10/11/2011

Summary of Pre-Clinical Testing

- *Axial Pullout Strength Evaluation* was conducted on the CONQUEST FN Locking screws. 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.
- *Insertion Torque Performance* was conducted on the proposed locking screws. Results of the testing concluded that the CONQUEST FN screws met the acceptance criteria and exhibited similar or superior insertion torque performance compared to the predicate.
- *Removal Torque Performance* was conducted on the CONQUEST FN Locking screws. Results of the test concluded that the subject device met the acceptance criterion and is expected to have acceptable torsional performance with regard to removal torque.
- *Torsional Strength Evaluation* was conducted on the CONQUEST FN Locking Screws. Results of the test concluded that the CONQUEST FN Locking Screws met the acceptance criteria and exhibited similar or superior torsional strength compared to the predicate.
- *Construct Fatigue Testing* was conducted on the CONQUEST FN System. Results of the test concluded that the CONQUEST FN system met the acceptance criteria and is expected to have similar construct stability during bending fatigue as compared to the predicate.
- *Construct Fatigue Evaluation* of the CONQUEST FN System as compared to Three Cannulated Screws in a Simulated Femoral Neck Fracture Model. Results of the test concluded that the CONQUEST FN System met the acceptance criteria and exhibited similar or superior construct fatigue as compared to the predicate.
- *Construct Fatigue Evaluation* was conducted on the one hole CONQUEST FN locking plate as compared to Three Cannulated Screw. Results of the test concluded that the CONQUEST FN one hole locking plate met the acceptance criteria by having at least similar or superior construct fatigue performance as compared to the predicate.

Conclusion

This 510(k) premarket notification is being submitted to request clearance for CONQUEST FN. Based on the similarities to the predicate components and a review of the mechanical testing performed, the devices are substantially equivalent to the predicate systems listed in *Table 1*.