February 28, 2020

K193029
Smith & Nephew, Inc.
1450 E Brooks Rd, Memphis, TN 38116 US
Trade/Device Name: CONQUEST FN
Contact Name: Thomas Fearnley
Senior Regulatory Affairs Specialist

Re: K193029
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: January 24, 2020
Received: January 27, 2020

Dear Thomas Fearnley:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for

devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Vesa Vuniqi, MS
Assistant Director
DHT6A: Division of Joint Arthroplasty Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K193029

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.

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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:	October 29, 2019
Contact Person and Address:	Thomas Fearnley Senior Regulatory Affairs Specialist T (901) 399-1224 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 sizes of the bone plates 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 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.

Comparison to Technological Characteristics with Predicate Device

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

The subject bone plates feature characteristics very similar to the CONQUEST FN system bone plates cleared via K152686, with the primary differences being the elimination of the plate shaft and distal screw holes. All other design aspects, indications for use, intended use, material and fundamental scientific technology remain the same as those in K152686.

Substantial Equivalence Information

The substantial equivalence of the CONQUEST FN 3 Hole Small Stature Plate 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 3 Hole Small Stature Plate

Manufacturer	Description	Submission Number	Clearance Date
Smith & Nephew	CONQUEST FN ***(Primary Predicate)***	K152686	3/17/2016
Smith & Nephew	Smith & Nephew Cannulated Screws and Washers	K111994	10/11/2011

A comparison of the subject device to the predicate device is described in the following table.

Table 5.2 Summary of Comparison to Predicate Devices

Design Aspect Reviewed	CONQUEST FN 3 Hole Small Stature Plate	CONQUEST FN (primary predicate)	Cannulated Screws and Washers
Predicate Type	N/A	Primary	Reference
510(k) Number	Subject 510(k)	K152686	K111994
Same intended use	Yes	Yes	Yes
Same Indications for Use	The Smith & Nephew CONQUEST FN is indicated for displaced and undisplaced intracapsular femoral neck fractures	The Smith & Nephew CONQUEST FN is indicated for displaced and undisplaced intracapsular femoral neck fractures	The Smith & Nephew Cannulated Screws and Washers are used for adult and pediatric patients as indicated for pelvic, small, and long bone fracture fixation.
Similar Operating Principle	Yes	Yes	No
Raw material type	316L Stainless Steel	316L Stainless Steel	316L Stainless Steel
Similar design features, function and intended use	Yes	Yes	No
Anatomically based Femoral Locking Plate	Yes	Yes	No
Screws	7.5 and 8.5mm Locking Screws (based on POGO Screw design K080649, up to 3)	7.5 and 8.5mm Locking Screws (based on POGO Screw design K080649, up to 3) 4.5mm locking and non-locking screws	4.0mm, 5.5mm, 6.5mm, 7.0mm and 8.0mm Cannulated Screws

Summary of Pre-Clinical Testing

- Construct Fatigue Testing was conducted on the CONQUEST FN 3 Hole Small Stature Plate. Results of the test concluded that the CONQUEST FN 3 Hole Small Stature Plate met the acceptance criteria and is expected to have similar construct stability during bending fatigue as compared to the predicate.

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.

Conclusion

The proposed additional sizes of CONQUEST FN plates are substantially equivalent to the previously cleared CONQUEST FN plates cleared with the CONQUEST FN system in K152686 in that the indications for use and fundamental scientific technology for the subject devices are identical.