February 17, 2023

Smith & Nephew Inc
Dongeun Lopresti
Senior Regulatory Affairs Specialist
150 Minuteman Road
Andover, Massachusetts 01810

Re: K222971
Trade/Device Name: ULTRABUTTON QUAD Adjustable Fixation Device; ULTRABUTTON BB Adjustable Fixation Device; ULTRABUTTON TIB Adjustable Fixation Device
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: MBI
Dated: September 26, 2022
Received: September 27, 2022

Dear Ms. Dongeun Lopresti:

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,

Sara S. Thompson -S

For

Laura C. Rose, Ph.D.
Assistant Director
DHT6C: Division of Restorative, Repair and Trauma 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222971

Device Name
ULTRABUTTON◊ QUAD Adjustable Fixation Device;
ULTRABUTTON BB Adjustable Fixation Device;
ULTRABUTTON TIB Adjustable Fixation Device

Indications for Use *(Describe)*
The ULTRABUTTON QUAD, BB, and TIB Adjustable Fixation Devices are indicated for soft tissue to bone or bone-tendon to bone fixation for: ACL/PCL Repair/Reconstruction and soft tissue to bone fixation for Extracapsular Repair: MCL, LCL.

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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510(k) Summary

February 16, 2023

Submitter Information	Contact Information
Smith & Nephew, Inc. Endoscopy Division 150 Minuteman Road Andover, MA 01810	Ms. Dongeun LoPresti Senior Regulatory Affairs Specialist (412)-683-3844

Device Name & Classification	
Proprietary Name	ULTRABUTTON◇ QUAD Adjustable Fixation Device ULTRABUTTON BB Adjustable Fixation Device ULTRABUTTON TIB Adjustable Fixation Device
Common Name	Fastener, Fixation, Nondegradable, Soft Tissue
Classification Name	Smooth or threaded metallic bone fixation fastener
Classification Regulation	21 CFR 888.3040
Class	2
Product Code	MBI
Panel	Orthopedic Devices (OHT6)

Legally Marketed Predicate Device

The Smith & Nephew ULTRABUTTON QUAD, BB, and TIB Adjustable Fixation devices are substantially equivalent in intended use and fundamental scientific technology to the following legally marketed predicate device:

Description	Submission Number	Clearance Date
Adjustable Fixation Device	K153186	January 1, 2016

Device Description

The Smith & Nephew ULTRABUTTON QUAD, BB, and TIB Adjustable Fixation Devices consist of an ultra-high molecular weight polyethylene graft suspension loop and a titanium cortical button. The devices facilitate knee ligament repair/reconstruction through placement and retention of soft tissue or bone-tendon within bone.

The ULTRABUTTON QUAD Adjustable Fixation Device and the ULTRABUTTON BB Adjustable Fixation Device is available in one size. The UTLRABUTTON TIB Adjustable Fixation Device is available in a small, medium, or large size.

Intended Use

The ULTRABUTTON QUAD, BB, and TIB Adjustable Fixation Devices are intended for soft tissue to bone or bone-tendon to bone fixation.

Indications for Use

The ULTRABUTTON QUAD, BB, and TIB Adjustable Fixation Devices are indicated for soft tissue to bone or bone-tendon to bone fixation for: ACL/PCL Repair/Reconstruction and soft tissue to bone fixation for Extracapsular Repair: MCL, LCL.

Technological Characteristics

The Smith & Nephew ULTRABUTTON QUAD, BB, and TIB Adjustable Fixation Devices are substantially equivalent to the predicate Smith & Nephew Adjustable Fixation Device (K153186). Technological characteristics such as intended use, indications for use, sterilization method, and shelf-life are identical to the predicate device. There are minor changes in technological characteristics, such as design and material, compared to the predicate device. However, performance data demonstrates that the ULTRABUTTON QUAD, BB, and TIB Adjustable Fixation Devices are substantially equivalent to the predicate device in these regards, and raise no new or different questions of safety and effectiveness.

Summary of Performance Data

- Device cyclic displacement, device repair strength, and construct stiffness met the acceptance criteria established by the predicate device (K153186).
- Biocompatibility testing per ISO 10993-1:2018 demonstrated passing results.
- Bacterial endotoxin testing was completed and met acceptable limits per ANSI/AAMI ST72:2019.
- The devices have a three (3) year shelf-life. Storage and stability is based on completed packaging material storage stability testing, device storage stability testing, and distribution testing. Packaging testing per ISO 11607-1:2019 demonstrated passing results.
- Sterile adoption was completed per ISO 11135:2014+A1:2018.

Conclusion

There is no change in intended use, indications for use, sterilization method, and shelf-life. Changes in design and material are minor, and do not raise new or different questions of safety and effectiveness compared to the predicate device. The non-clinical testing has demonstrated that the ULTRABUTTON QUAD, BB, and TIB Adjustable Fixation Devices are substantially equivalent to their predicate device.