March 12, 2019

Smith and Nephew, Inc.
Dharaben Desai
Regulatory Affairs Specialist II
150 Minuteman Road
Andover, Massachusetts 01810

Re: K183232
Trade/Device Name: Double ENDOBUTTON Fixation Device
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HTN, HWC
Dated: February 7, 2019
Received: February 8, 2019

Dear Ms. Desai:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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,

Laurence D. Coyne -S

For 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K183232

Device Name
Double ENDOBUTTON Fixation Device

Indications for Use *(Describe)*
The Double ENDOBUTTON Fixation Device is intended for the treatment of anterior glenoid bone loss using the Latarjet or bone block procedure (allograft or autograft).

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
Smith & Nephew Double ENDOBUTTON Fixation Device

Submitted by: Smith & Nephew, Inc.
Advanced Surgical Devices Division
150 Minuteman Road
Andover, MA 01810

Date of Submission: February 6, 2019

Contact Person: Dharaben Desai, Regulatory Affairs Specialist II
T (901) 281-8073
F (901) 566-7598

Name of Device: Smith & Nephew, Inc. Double ENDOBUTTON Fixation Device

Common Name: Washer, Bolt Nut
Screw, Fixation, Bone

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: HTN, HWC

Predicate Device: Arthrex Low Profile Screws (3.5mm and larger, cannulated) – K103705
Smith & Nephew Ultraslide Acromioclavicular and Syndesmotic Repair Device – K082095

510(k) SUMMARY
Smith & Nephew Double ENDOBUTTON Fixation Device

Device Description:

The subject of this Traditional 510(k) is the Double ENDOBUTTON Fixation Device. The Smith & Nephew Double ENDOBUTTON Fixation Device is used during the healing period of osteotomies for orthopedic reconstruction and to assist in the management of fracture fixation. The device consists of three components: two stainless steel fixation devices and a UHMW polyethylene suture. This device is provided sterile, for single use only.

Indications for Use

The Double ENDOBUTTON Fixation Device is intended for the treatment of anterior glenoid bone loss using the Latarjet or bone block procedure (allograft or autograft).

Technological Characteristics

The Smith & Nephew Double ENDOBUTTON Fixation Device is substantially equivalent to the predicate screws despite the differences in technological characteristics and design. Performance data and clinical results demonstrate this equivalence and show the subject device does not raise any new issues of safety and efficacy. The technological characteristics comparison between the subject device and predicate devices is provided below.

Table 1: Summary of Technological Characteristics

Technological Characteristics	**Double ENDOBUTTON Fixation Device- Subject device**	**Arthrex Low Profile Screws (3.5mm and larger, cannulated)- K103705**	**Smith & Nephew Ultraslide Acromioclavicular and Syndesmotic Repair Device- K082095**
Components	Two ENDOBUTTONS and suture	Screw	Two ENDOBUTTONS and suture

510(k) SUMMARY
Smith & Nephew Double ENDOBUTTON Fixation Device

Material	Stainless Steel ENDOBUTTONS, UHMWPE Suture	Titanium or Stainless Steel screw	Titanium ENDOBUTTONS, UHMWPE Suture
Labeling	Sterile, single-use only, Rx only	Non-sterile, single-use only, Rx only	Sterile, single-use only, Rx only
Sterilization Method	Gamma or EtO	Non-sterile	EtO

Performance Data

Mechanical testing demonstrates the device has met the performance specifications for the mechanical integrity of the Smith & Nephew Double ENDOBUTTON Fixation Device. The following performance testing was used as a basis for the determination of substantial equivalence.

- Interface pressure test
- Suture construct test with open ended suture lines
- Closed loop suture test
- Suture construct tests with closed looped suture lines

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.

Substantial Equivalence Information

The Smith & Nephew Double ENDOBUTTON Fixation Device is substantially equivalent in intended use and fundamental scientific technology to the following legally marketed devices in commercial distribution:

Table 2: Predicate Devices

510(k) SUMMARY
Smith & Nephew Double ENDOBUTTON Fixation Device

Manufacturer	Description	Submission Number	Clearance Date
Arthrex, Inc.	Low Profile Screws (3.5mm and larger, cannulated)	K103705	03/18/2011
Smith & Nephew	Ultraslide Acromioclavicular and Syndesmotic Repair Device	K082095	10/21/2008

Clinical Data

A clinical literature review was completed to compare the subject devices and screws. The literature available for the Double ENDOBUTTON or screws for glenoid bone loss in the shoulder was reviewed. In the literature review, total of 299 joints in 299 patients were treated with a Double ENDOBUTTON, and 1,895 joints in 1,886 patients with various screws.

The complication rate reported after use of the Double ENDOBUTTON compared favorably to screws in most complications such as revision (0% compared to 0.85-11.49% respectively), device migration(0% compared to 5.26-21.43% respectively), device breakage (0% compared to 4.68% respectively) and graft migration (4.5% compared to 3.0-14.89% respectively). No device migrations, breakages, loosening or removals were noted in the publications that reported results of patients treated with the Double ENDOBUTTON.

Clinical outcome scores such as ROWE and Walch-Duplay reported for the subject Double ENDOBUTTON device were similar to those reported by screws. In patients treated with screws, postoperative ASES scores ranged from 86.3 to 93.3 and postoperative ROWE scores ranged from 78.1 to 97.1. In patients treated with the Double ENDOBUTTON, postoperative ROWE score ranging from 81 to 95.3 and Walch-Duplay scores ranged from 80 to 96. Postoperative Walch-Duplay scores for patients treated with screws ranged from 76.7 to 91.7.

Conclusion

As previously noted, this Traditional 510(k) Premarket Notification is being submitted to request clearance for the Smith & Nephew Double ENDOBUTTON Fixation Device.

510(k) SUMMARY
Smith & Nephew Double ENDOBUTTON Fixation Device

Based on the similarities to the predicate components and a thorough review of the clinical and mechanical testing, the devices are substantially equivalent to above predicate devices.