DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

December 7, 2016

Smith and Nephew, Inc.
Ms. Anne-Marie Keefe
Senior Regulatory Affairs Specialist
150 Minuteman Road
Andover, Massachusetts 01810

Re: K163034
Trade/Device Name: SUTUREFIX Curved Suture Anchor
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: MBI
Dated: October 28, 2016
Received: October 31, 2016

Dear Ms. Keefe:

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 Parts 801 and 809]); 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
Division Director
Division of Orthopaedic 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)*
K163034

Device Name
SUTUREFIX Curved Suture Anchor

Indications for Use *(Describe)*
The Smith & Nephew SUTUREFIX Curved Suture Anchors are intended for the secure fixation of soft tissue to bone for the following indications:

Hip
• Acetabular labrum repair/reconstruction

Shoulder
• Capsular stabilization
– Bankart repair
– Anterior shoulder instability
– SLAP lesion repairs
– Capsular shift or capsulolabral reconstructions
– Rotator cuff tear repairs
– Bicepts tenodesis

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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Endoscopy
Smith & Nephew, Inc.
150 Minuteman Road
Andover, MA 01810 USA

T 978-749-1000
F 978-749-1443
www.smith-nephew.com

We are smith&nephew

510(k) Summary

Prepared: 29 November 2016

Submitter Information	Contact Information
Smith & Nephew, Inc. Endoscopy Division 150 Minuteman Road Andover, MA 01810	Anne-Marie Keefe Senior Regulatory Affairs Specialist Phone: (508) 261-3713 Fax: (978) 749-1443

Device Name & Classification	
Proprietary Name	SUTUREFIX Curved Suture Anchor
Common Name	Soft Tissue Fixation Device
Classification Name	Fastener, fixation, nondegradable, soft tissue
Classification Regulation	21 CFR 888.3040
Class	II
Product Code(s)	MBI
Panel	Orthopedic

Legally Marketed Predicate Devices

The Smith & Nephew SUTUREFIX Curved Suture Anchor is substantially equivalent in intended use and Fundamental Scientific Technology to the following legally marketed devices in commercial distribution:

Description	Submission Number	Clearance Date
SUTUREFIX All Suture Anchor	K122059	March 18, 2013
BIORAPTOR 2.3 PK Suture Anchor	K102660	December 13, 2010

Device Description

The Smith & Nephew SUTUREFIX Curved suture anchor system consists of an all suture based implant, hole preparation, and curved insertion accessory instruments. The implant will be offered in multiple suture configurations including single and double loaded suture options. The instruments will include sterile flexible drills and reusable curved drill guides and obturators.

Intended Use

The Smith & Nephew SUTUREFIX Curved Suture Anchors are intended for the secure fixation of soft tissue to bone for the following indications:

Hip
• Acetabular labrum repair/reconstruction

Shoulder
• Capsular stabilization
– Bankart repair
– Anterior shoulder instability
– SLAP lesion repairs
– Capsular shift or capsulolabral reconstructions
– Rotator cuff tear repairs
– Bicepts tenodesis

Technological Characteristics

The Smith & Nephew SUTUREFIX Curved Suture Anchor is substantially equivalent in intended use and fundamental scientific technology to the legally marketed predicate devices - Smith and Nephew SUTUREFIX Ultra Suture Anchor (K122059), and the BIORAPTOR 2.3 PK Suture Anchor (K102660), and raises no new issues of safety and efficacy. The Smith & Nephew SUTUREFIX Curved Suture Anchor and the predicate SUTUREFIX Ultra Suture Anchor use the identical component materials, and all-suture based implant configurations. The Smith & Nephew SUTUREFIX Curved Suture Anchor and the predicate BIORAPTOR 2.3 PK Suture Anchor share the same curved, anchor delivery system.

Summary Performance Data

Bacterial endotoxin testing was completed and met acceptable endotoxin limits per ANSI/AAMI ST72:2011. Performance data demonstrates that the SUTUREFIX Curved Suture Anchor has met performance specifications for insertion strength and pull-out strength and therefore, is considered substantially equivalent to the currently marketed predicate devices.

Substantial Equivalence Information

The substantial equivalence of the SUTUREFIX Curved Suture Anchor is based on similarities in indications for use, design features, operational principles, material biocompatibility and composition, and performance to the predicate devices listed above. Based on the similarities to the predicates, the SUTUREFIX Curved Suture Anchor is substantially equivalent to its predicates.