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Submitted by:	Smith & Nephew, Inc. Advanced Surgical Devices Division 150 Minuteman Road Andover, MA 01810
Date of Summary:	May 12, 2014
Contact Person and Address:	Katherine Marcaccio Regulatory Affairs Specialist II T (508) 261-3602 F (978) 749-1443
Name of Device:	Smith & Nephew Cannulated Captured Screw
Common Name:	Screw, Fixation, Bone
Device Classification Name and Reference:	21 CFR 888.3040 Smooth or threaded metallic bone fixation fastener
Device Class:	Class II
Panel Code:	Orthopaedics/87
Product Code:	HWC

Device Description

The Smith & Nephew Cannulated Captured Screw is used during the healing period of osteotomies for orthopedic reconstruction and to assist in the management of fracture fixation. The device consists of a titanium alloy or stainless steel fixation device. This device is provided sterile, for single use only.

Indications for Use

The Smith & Nephew Cannulated Captured Screw is intended for use for internal bone fixation including fractures of the tibia, fibula, clavicle, scapula, olecranon, metacarpals, metatarsals, humerus, ulna, middle hand bones, middle foot bones, and calcaneous. Screws are additionally intended for arthrodeses and osteotomies of small bones and small joints including scaphoid and other carpal bones, metacarpals, tarsals, metatarsals, clavicle, scapula, olecranon, ulnar styloid, radial head, and radial styloid.

Technological Characteristics

The Smith & Nephew Cannulated Captured Screw is substantially equivalent in design and fundamental scientific technology to the defined predicate device and does not raise any new issues of safety and efficacy.

Performance Data

Mechanical testing, including insertion torque, pull-out strength, static torsional strength, and three-point bend fatigue testing, demonstrates the device has met the performance specifications for the torsional, and compression capabilities of the Smith & Nephew Cannulated Captured Screw; therefore, it is considered substantially equivalent to the currently marketed predicate device.

Substantial Equivalence Information

The Smith & Nephew Cannulated Captured Screw is substantially equivalent in intended use and fundamental scientific technology to the following legally marketed predicate device:

Table 1: Substantially Equivalent Predicate to the Cannulated Captured Screw

Manufacturer	Description	Submission Number	Clearance Date
Arthrex, Inc.	Low Profile Screws	K103705	3/18/2011

Conclusion

As previously noted, this Traditional 510(k) Premarket Notification is being submitted to request clearance for the Smith & Nephew Cannulated Captured Screw. Based on the similarities to the predicate components and a review of the mechanical testing performed, the devices are substantially equivalent to above predicate device.

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

May 15, 2014

Smith & Nephew, Incorporated
Ms. Katherine Marcaccio
Regulatory Affairs Specialist II
150 Minuteman Road
Andover, Massachusetts 01810

Re: K133662
Trade/Device Name: Smith & Nephew Cannulated Captured Screw
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC
Dated: April 14, 2014
Received: April 15, 2014

Dear Ms. Marcaccio:

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); 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" (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 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,

Ronald P. Jean -S for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Premarket Notification
Indications for Use Statement

510(k) Number (if known): K133662

Device Name: Smith & Nephew Cannulated Captured Screw

Indications for Use:

The Smith & Nephew Cannulated Captured Screw is intended for use for internal bone fixation including fractures of the tibia, fibula, clavicle, scapula, olecranon, metacarpals, metatarsals, humerus, ulna, middle hand bones, middle foot bones, and calcaneous. Screws are additionally intended for arthrodeses and osteotomies of small bones and small joints including scaphoid and other carpal bones, metacarpals, tarsals, metatarsals, clavicle, scapula, olecranon, ulnar styloid, radial head, and radial styloid.

Prescription Use __X__ AND/OR Over-the-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth L Frank -S

Division of Orthopedic Devices

Exhibit 2-2