K060736

510(k) Summary of Safety and Effectiveness

APR 18 2006

Smith & Nephew 6.5mm and 8.0mm Cannulated Screws

Submitted by: Smith & Nephew, Inc.
Orthopaedic Division
1450 Brooks Road
Memphis, TN 38116

Date: March 17, 2006

Contact Person: David Henley, Senior Regulatory Affairs Specialist
Proprietary Name: **Smith & Nephew 6.5mm and 8.0mm Cannulated Screws**
Common Name: Bone Screw
Classification Name and Reference: 21 CFR 888.3040 – Smooth or threaded metallic bone fixation fastener, Class II
Device Product Code and Panel Code: HWC / Orthopaedics / 87

Device Description:
The subject devices are line additions to the Smith & Nephew Bone Plate System. These line additions are comprised of *6.5mm and 8.0mm diameter Cannulated Screws*, which are self-tapping and self-drilling screws with a cancellous thread that can be guided into position through use of a guide-wire. These devices are available *partially or fully threaded*. *Partially threaded* Cannulated Screws are available in overall lengths ranging from 30mm - 180mm and with thread lengths of 16mm, 24mm, 40mm and 47mm. *Fully threaded* Cannulated Screws are available in overall lengths ranging from 30mm - 180mm. Three washer configurations will also be made available as accessory items. **Smith & Nephew 6.5mm and 8.0mm Cannulated Screws** are manufactured from stainless steel and titanium materials.

Indications for Use:
Smith & Nephew Bone Plate System is used for adult and pediatric patients as indicated for pelvic, small and long bone fracture fixation. Indications for use include fractures of the tibia, fibula, femoral condyle, pelvis, acetabulum, metacarpals, metatarsals, humerus, ulna, middle hand and middle foot bones; treatment of the calcaneal; hip arthrodesis, and provisional bone fixation.

Smith & Nephew 6.5mm and 8.0mm Cannulated Screws are for single use only.

Technological Characteristics:
The principle of operation of the subject devices is identical to that of the predicates. There are no changes in intended use, performance specifications or method of operation. A review of the test data for the subject devices indicates that they are equivalent to the predicate devices currently in clinical use and are capable of withstanding expected *in vivo* loading without failure.

Substantial Equivalence Information:
Substantial equivalence for **Smith & Nephew 6.5mm and 8.0mm Cannulated Screws** is based on its similarities in indications for use, design features, operational principles, and material composition when compared to the predicate devices cleared under the following submissions:

K993106, Smith & Nephew Bone Plate System;
K903810, Ace Medical Cannulated Screw;
K000080, Howmedica Osteonics ASNIS III Cannulated Screw System; and
K051296, DePuy Spine Inc. SIJF Cannulated Screw System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 18 2006

Smith & Nephew, Inc.
Orthopaedic Division
c/o Mr. David Henley
Senior Regulatory Affairs Specialist
1450 Brooks Road
Memphis, Tennessee 38116

Re: K060736
Trade/Device Name: Smith & Nephew 6.5mm and 8.0mm Cannulated Screws
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HWC
Dated: March 17, 2006
Received: March 20, 2006

Dear Mr. Henley:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Premarket Notification
Indications for Use Statement

510(k) Number (if known): K060736

Device Name: Smith & Nephew 6.5mm and 8.0mm Cannulated Screws

Indications for Use:

The Smith & Nephew Bone Plate System is used for adult and pediatric patients as indicated for pelvic, small and long bone fracture fixation. Indications for use include fractures of the tibia, fibula, femoral condyle, pelvis, acetabulum, metacarpals, metatarsals, humerus, ulna, middle hand and middle foot bones; treatment of the calcaneal; hip arthrodesis, and provisional bone fixation.

Smith & Nephew 6.5mm and 8.0mm Cannulated Screws are for single use only.

Prescription Use ___X___ and/or Over-the-Counter Use _____
(Per 21 CFR 801, 109) (Optional Format 1-2-96)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K060736