K081491

510(k) Summary of Safety and Effectiveness

JUN 19 2008

Submitted by:

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

Date: 5/27/2008

Contact Person:

Mason W. Robbins, RPCV
Regulatory Affairs Specialist

Proprietary Name: Smith & Nephew CDS System
Common Name: Discography System
Classification Name and Reference: Image-intensified fluoroscopic x-ray system
21 CFR 892.1650

Device Product Code and Panel Code: JAA/Radiology/90

Device Description:
The Smith & Nephew CDS System consists of a control unit with a fluid delivery module with user interface, a remote control and a sterile, single-use fluid delivery syringe, tube set and remote sleeve.

Intended Use:
The Smith & Nephew CDS System is intended to dispense and monitor the pressure of fluids during spinal procedures such as discography.

Technological Characteristics:
The proposed Smith & Nephew CDS System is substantially equivalent to the predicate Smith & Nephew CDS System (K051136). The proposed CDS System remote control underwent firmware and hardware modifications to improve its performance and reliability.

Substantial Equivalence Information:
The changes made to the proposed CDS System represent improvements that will improve its performance over the predicate CDS System (K051136). The proposed CDS System is substantially equivalent to its predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 19 2008

Mr. Mason W. Robbins
Regulatory Affairs Specialist
Smith & Nephew, Inc.
Orthopaedic Division
1450 East Brooks Road
MEMPHIS TN 38116

Re: K081491
Trade/Device Name: Smith & Nephew CDS System
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: JAA
Dated: May 27, 2008
Received: May 28, 2008

Dear Mr. Robbins:

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, 1796, 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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Premarket Notification
Indications for Use Statement

510(k) Number (if known):

Device Name: Smith & Nephew CDS System

Indications for Use:

The Smith & Nephew CDS System is intended to dispense and monitor the pressure of fluids during spinal procedures such as discography.

Prescription Use __X__ (Per 21 CFR 801.109) OR Over-the-Counter Use _____ (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 Reproductive, Abdominal, and Radiological Devices
510(k) Number K081491