K051136

JUL 1 - 2005

SECTION IV

510(k) SUMMARY

Date Prepared: May 2, 2005

A. Submitter's Name:

Smith & Nephew, Inc., Endoscopy Division

150 Minuteman Road

Andover, MA 01810

B. Company Contact:

Diane Minear

Director, Regulatory Affairs

Phone: 978-749-1441

Fax: 978-749-1443

C. Device Name

Trade Name:	Smith & Nephew CDS System
Common Name:	Discography System
Classification Name:	Image-intensified ~~Photo~~fluorographic X-ray System ~~Accessory~~ 892.1730 1650

D. Predicate Devices

The Smith & Nephew CDS System is substantially equivalent in intended use and fundamental scientific technology to the following legally marketed device in commercial distribution: The Integra® Spinal Specialties Accu-Disc® Pressure Monitoring Syringe - K960082.

E. Description of Device

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.

F. Intended Use

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

G. Comparison of Technological Characteristics

The Smith & Nephew CDS System is substantially equivalent in function and intended use to the Integra® Spinal Specialties Accu-Disc® Pressure Monitoring Syringe - K960082. The main technological difference between the two devices is that the Smith & Nephew device is an automated system with data display and storage capacity and the Integra device is operated manually.

G. Summary Performance Data

The Smith & Nephew CDS System meets the biocompatibility requirements of ISO 10993-1 and electrical safety standards in UL 60601-1, IEC 60601-1-1, and IEC 60601-1-2 and EN 55011. Software verification and validation testing and additional bench performance testing all demonstrate that the Smith & Nephew CDS System is as safe and effective, and performs at least as well as the legally marketed devices for the same intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 1 - 2005

Ms. Diane E. Minear
Director, Regulatory Affairs
Smith & Nephew, Inc.
Endoscopy
150 Minuteman Road
ANDOVER MA 01810

Re: K051136
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 2, 2005
Received: May 9, 2005

Dear Ms. Minear:

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 (Premarket Approval), 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 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" (21 CFR 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/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

Indications for Use

510(k) Number (if known): K051136

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 ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K051136