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

K070266

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510(k) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION as required by the Safe Medical Devices Act of 1990 and codified in 21 CFR 807.92 upon which the substantial equivalence is based.

Smith & Nephew HD Camera System
Date Prepared: January 26, 2007

FEB 2 2 2007

A. Submitter's Name:

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

B. Company Contact

Janice Haselton
Sr. Regulatory Affairs Specialist
Phone: (978)749-1494
Fax: (978)749-1443

C. Device Name

Trade Name:	Smith & Nephew HD Camera System
Common Name:	Endoscopes and accessories
Classification Name:	Laparoscope, General & Plastic Surgery

D. Predicate Devices

The Smith & Nephew HD Camera System is substantially equivalent in Intended Use and Fundamental Scientific Technology to the following legally marketed device in commercial distribution:

E. Description of Device

The Smith & Nephew HD Camera System is used in endoscopic surgical procedures to capture and transmit video images. The Smith & Nephew HD Camera System consists of a camera control unit and a camera head. The camera system has been designed to be capable of outputting a true high definition picture. The high definition picture is maintained by continuous transmission of high resolution output from the camera head to the camera control unit.

F. Intended Use

The Smith & Nephew HD Camera System is indicated for use in endoscopic surgical procedures to allow visualization of the articular cavities, body cavities, hollow organs and canals when used with an appropriately indicated endoscope.

Additionally, when used in conjunction with a Smith & Nephew light source and light cable the Smith & Nephew HD Camera System is indicated for use in endoscopic surgical procedures in the thoracic cavity when used with an appropriately indicated thoracoscope.

G. Comparison of Technological Characteristics

The Smith & Nephew HD Camera System similarities to the predicate device are:

- has the same Indications for Use
- utilizes the same operating principle
- incorporates the same basic design
- it is manufactured under a Quality System
- incorporates the same technological characteristics as the predicate

H. Summary Performance Data

The performance testing, EMI/EMC testing, UL Safety testing and the software verification and validation conducted on the Smith & Nephew HD Camera System demonstrates substantial equivalence to the DYONICS Vision 325Z DV 3-CCD Hermes-Ready Camera System cleared in K031379. The testing also demonstrates that any differences in the new device and the predicate device do not raise any new issues of safety and efficacy and that the Smith & Nephew HD Camera System performs as well as the legally marketed device.

The Smith & Nephew HD Camera System conforms to the following voluntary standards:

IEC 60601-1 Medical Electrical Equipment – Part 1: General Requirements for Safety (1998) + Amendment 1 (1991) + Amendment 2 (1995) (UL 2601-1)

IEC 60601-1-1 Medical Electrical Equipment – Part 1: General Requirements for Safety; Safety Requirements for Medical Electrical Systems (1992) + Amendment 1 (1995), (2000)

IEC 60601-1-2 (2001-09) 2nd Edition Medical Electrical Equipment – Part 1: General Requirements for Safety; Electromagnetic Compatibility – Requirements & Tests (2001)

UL 60601-1 (2003): Medical Electrical Equipment – Part 1: General Requirements for Safety

CAN/CSA 22.2 No. 601.1 Medical Electrical Equipment – Part 1: General Requirements for Safety (1990) + Supplements No. 1-94 (1994)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Smith & Nephew
% Ms. Janice Haselton
Senior Regulatory Affairs Specialist
150 Minuteman Road
Andover, Massachusetts 01810

FEB 22 2007

Re: K070266
Trade/Device Name: 560 High Definition Camera System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: January 26, 2007
Received: January 29, 2007

Dear Ms. Haselton:

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.

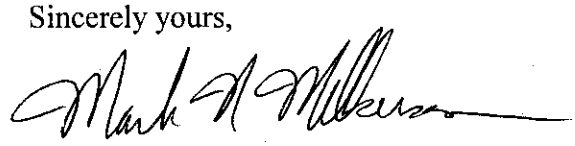
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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) 276-0115 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.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

K070266

§I.G

Indications for Use

510(k) Number (if known): _____

Device Name: _____Smith & Nephew HD Camera System_____

Indications For Use:

The Smith & Nephew HD Camera System is indicated for use in endoscopic surgical procedures to allow visualization of the articular cavities, body cavities, hollow organs and canals when used with an appropriately indicated endoscope.

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Mark N Milkerson

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

510(k) Number K070266

Prescription Use ___x_____ AND/OR Over-The-Counter Use _
(Per 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)