K032680 1/2

SEP 26 2003

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

978 749 1000
978 749 1599 Fax
www.smith-nephew.com

We are

**Exhibit F**

**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 300XL Xenon Illuminator-HERMES Ready device**
Date Prepared: August 28, 2003

**A. Submitter's Name:**

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

**B. Company Contact:**

Deborah Connors
Regulatory Affairs Manager
Phone: (978)749-1495
Fax: (978)749-1443

**C. Device Name**

Trade Name: Smith & Nephew 300XL Xenon Illuminator-HERMES Ready
Common Name: Endoscopic Light Source
Classification Name: General and Plastic Surgery

**D. Predicate Devices**

The Smith & Nephew 300XL Xenon Illuminator-HERMES Ready device is substantially equivalent in Intended Use and Fundamental Scientific Technology to the following legally marketed device(s) in commercial distribution: Smith & Nephew 300XL Xenon Illuminator.

**E. Description of Device**

The Smith & Nephew 300 XL Illuminator – HERMES Ready is a 300 Watt Xenon Illuminator indicated for use in endoscopic surgical procedures. The Hermes-Ready™ feature will enable voice and pendant control of light intensity, manual and

automatic mode control and standby and activation mode control from a central location when used in conjunction with a Hermes™ Digital O.R. Control Center.

## F. Intended Use

The Smith & Nephew Illuminators are indicated for use in endoscopic surgical procedures to provide illumination of articular cavities, body cavities, hollow organs and canals when used in conjunction with an appropriately indicated endoscope.

The Smith & Nephew Illuminators are indicated for use in endoscopic surgical procedures in the thoracic cavity when used in conjunction with an appropriately indicated endoscope.

## G. Comparison of Technological Characteristics

The Smith & Nephew 300XL Xenon Illuminator-HERMES Ready device has the same technological characteristics and intended use as the predicate device, Smith & Nephew 300XL Xenon Illuminator. The addition of the communication interface for voice activation with the Hermes™ control center offers the surgeon direct communication without changing the intended use or features of the Smith & Nephew 300XL Xenon Illuminator.

Smith & Nephew 300XL Xenon Illuminator-HERMES Ready device will be tested with the following domestic and international standards:

- UL 2601-1: Standard for Medical Electrical Equipment, Part 1: General Requirements for Safety
- EN 60601-1: Standard for Medical Electrical Equipment, Part 1: General Requirements for Safety + Amendments1 and 2
- EN 60601-1-1: Medical Electrical Equipment General Requirements for Safety 1, Collateral Standard: Safety Requirements for Medical Electrical Systems
- EN 60601-1-2: Medical Electrical Equipment General Requirements for Safety2, Collateral Standard: Electromagnetic Compatibility- Requirements and Tests

## H. Summary Performance Data

All verification and validation data demonstrates that the device is safe and effective and performs as intended.

Deborah Connors
Regulatory Affairs Manager

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 26 2003

Ms. Deborah Connors
Regulatory Affairs Manager
Smith & Nephew, Inc.
150 Minuteman Road
Andover, Massachusetts 01810

Re: K032680
Trade/Device Name: Smith & Nephew 300XL Xenon Illuminator-HERMES Ready™
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ
Dated: August 28, 2003
Received: August 29, 2003

Dear Ms. Connors:

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 (301) 594-4659. 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,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K032680

Device Name: Smith & Nephew 300XL Xenon Illuminator-HERMES Ready™

Indications For Use: The Smith & Nephew Illuminators are indicated for use in endoscopic surgical procedures to provide illumination of articular cavities, body cavities, hollow organs and canals when used in conjunction with an appropriately indicated endoscope.

The Smith & Nephew Illuminators are indicated for use in endoscopic surgical procedures in the thoracic cavity when used in conjunction with an appropriately indicated endoscope.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use √ OR Over-The-Counter Use _____

(Per 21 CFR 801.109)

Miriam C. Provost

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

**510(k) Number** K032680