K031379

Endoscopy Division

Smith & Nephew, Inc.
150 Minuteman Road, Andover, MA 01810-1031 U.S.A.
Telephone: 978-749-1000
Fax: 978-749-1599

MAY 22 2003

Smith+Nephew

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.

Dyonics® Vision 325Z DV3-CCD Hermes -Ready™ Camera System

Date Prepared: April 28, 2003

A. Submitter's Name:

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

B. Company Contact:

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

C. Device Name

Trade Name: Smith & Nephew Dyonics® Vision 325Z DV Hermes-Ready™ Camera System
Common Name: Camera Control Unit
Classification Name: General and Plastic Surgery

D. Predicate Devices

The Smith & Nephew Dyonics® Vision 325Z DV Hermes-Ready™ CCD Color Video Camera System is substantially equivalent in Intended Use and Fundamental Scientific Technology to the following legally marketed device(s) in commercial distribution: Images Digital 3-Chip Color Video Camera.

E. Description of Device

The Smith & Nephew Dyonics® Vision 325Z DV Hermes- Ready™3 CCD Camera is used in endoscopic surgical procedures to capture and transmit video images. The Hermes-Ready™ feature will enable voice and pendant control of white balance, zoom, shutter control, enhancement and on/off ability from a central location when used in conjunction with a Hermes™ Digital O.R. Control Center.

F. Intended Use

The Smith & Nephew Dyonics® Vision 325Z DV 3-CCD Color Video 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 Dyonics® light source and light cable, the 325Z DV 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 Dyonics® Vision 325Z DV Hermes-Ready™ 3-CCD Color Video Camera System has the same technological characteristics and intended use as the predicate device, Smith & Nephew Images Digital 3-Chip Color Video Camera. The addition of 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 Dyonics® Vision 325Z DV 3-CCD Color Video Camera.
The Smith & Nephew Dyonics® Vision 325Z DV Hermes-Ready™ 3-CCD Color Video Camera System 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
- CAN/CSA – C22.2 No. 601.1-M90- Medical Electrical Equipment General Requirements for Safety: A National Standard for Canada

H. Summary Performance Data

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 22 2003

Ms. Janice Haselton
Regulatory Affairs Specialist II
Smith & Nephew, Inc.
Endoscopy Division
150 Minuteman Road
Andover, Massachusetts 01810

Re: K031379
Trade/Device Name: Dyonics® Vision 325Z DV 3-CCD Hermes-Ready Camera System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ
Dated: April 28, 2003
Received: May 1, 2003

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 (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. 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 may be obtained 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,

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): K031379

Device Name: Dyonics® Vision 325Z DV 3-CCD Hermes- Ready Camera System

Indications For Use:

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(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)

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

510(k) Number K031379