Endoscopy Division
Smith & Nephew, Inc.
160 Dascomb Road, Andover, MA 01810 U.S.A.
Telephone: 508-749-1000
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OCT 24 1997

510(k) Summary
Smith & Nephew Images Digital 3-Chip Color Video Camera, Illuminators, Video Components and Accessories

Smith+Nephew

K972471

Substantial Equivalence

The Smith & Nephew Images Surgical Camera, Illuminators, Video Components and Accessories are substantially equivalent in both design and intended use to surgical cameras, video components and illumination products offered by Snowden Pencer DSP, Stryker Endoscopy and Olympus.

The Video Components, Surgical Cameras, Illuminators and accessories for all of the above referenced manufacturers mate with an endoscope to allow for visualization during various surgical procedures. The Illuminators, Light Guides and accessories mate to the endoscope and deliver light to the surgical site.

Predicate Device:

The predicate devices for this submission are the current product offerings from Smith & Nephew as well as video components, surgical cameras, illuminators and accessories manufactured by Snowden Pencer DSP, Stryker Endoscopy and Olympus.

Summary of Device Function:

The Smith & Nephew Images Digital 3-Chip Color Video Camera and Video components mate with the endoscope to allow for visualization during various surgical procedures.

Smith & Nephew Images Illuminators, Light Guides and accessories are designed to supply light to the surgical site through the endoscope. The light guides mate to the endoscope and light source with instrument specific adapters.

Intended Use of Device:

Smith & Nephew Images Digital 3-Chip Color Video Camera System, illuminators, video components and accessories are indicated for use in endoscopic surgical procedures to provide illumination and allow visualization of articular cavities, body cavities, hollow organs and canals when used in conjunction with an appropriately indicated endoscope.

Additionally, the Smith & Nephew Images Digital 3-Chip Color Video Camera System, consisting of the D-3 Camera Control Unit (REF. 7205292), PEEK Camera Head (REF. 7205208), Smith & Nephew Images Illuminator and Smith & Nephew Images liquid or fiberoptic light guide is indicated for use in endoscopic surgical procedures in the thoracic cavity when used in conjunction with an appropriately indicated thoracoscope.

Comparison of Technological Characteristics of Predicate Devices:

The basic design and function of the Smith & Nephew Images Surgical Camera, Illuminators, Video Components and Accessories are unchanged compared to information provided in previous submissions. All electromechanical equipment complies with UL544, EN 55011, IEC 601-1 and IEC 601-2-18. The Smith & Nephew Images Digital 3-Chip Color Video Camera Head complies with the appropriate electrical safety standards for use in the thoracic cavity. Smith & Nephew Images Surgical Camera, Illuminators, Video Components and Accessories are substantially equivalent in both design and intended use to surgical cameras, video components and illumination products offered by Snowden Pencer DSP, Stryker Endoscopy and Olympus.

Deborah Connors
Regulatory Affairs Department

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 24 1997

Ms. Deborah J. Connors
Regulatory Affairs Specialists
Smith & Nephew, Inc.
160 Dascomb Road
Andover, Massachusetts 01810

Re: K972471
Trade Name: Smith & Nephew Endoscopy Images Digital 3-Chip Color Video Camera, Illuminators, Video Components and Accessories
Regulatory Class: II
Product Code: GCJ
Dated: September 23, 1997
Received: September 24, 1997

Dear Ms. Connors:

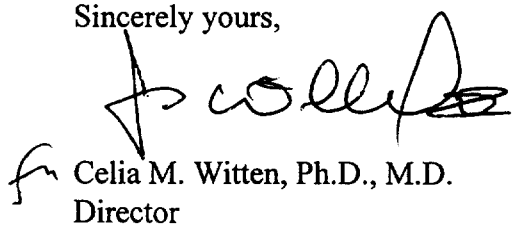
We have reviewed your Section 510(k) notification of intent to market the devices referenced above and we have determined the devices are substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date 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). You may, therefore, market the devices, 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 devices are classified (see above) into either class II (Special Controls) or class III (Premarket Approval), they may be subject to such additional controls. Existing major regulations affecting your devices can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements , as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your devices in the Federal Register. Please note: this response to your premarket notification submissions does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your devices as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your devices to a legally marketed predicate device results in a classification for your devices and thus, permits your devices to proceed to the market.

If you desire specific advice for your devices on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your devices, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,



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

Enclosure

510(k) Number : K972471

Device Name : Smith & Nephew, Inc., Endoscopy Division Images Digital 3-Chip Color Video Camera, Illuminators, Video Components and Accessories

Indications for Use :

Smith & Nephew Images Digital 3-Chip Color Video Camera System, illuminators, video components and accessories are indicated for use in endoscopic surgical procedures to provide illumination and allow visualization of articular cavities, body cavities, hollow organs and canals when used in conjunction with an appropriately indicated endoscope.

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(PLEASE DO WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K972471

Prescription Use X OR Over-the-Counter ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)