

**Endoscopy Division**

Smith & Nephew, Inc.  
160 Dascomb Road, Andover, MA 01810 U.S.A.  
Telephone: 508-749-1000  
Telefax: 508-749-1599

AUG 12 1997  
K971850

**Smith+Nephew**

**510(k) Summary**  
**Smith & Nephew, Inc., Endoscopy Division**  
**Images 5mm x 300mm Endoscope**

**Substantial Equivalence:**

The Smith & Nephew Images 5mm x 300mm Endoscope is substantially equivalent in design, materials, function, and intended use to the 5mm x 300mm telescope offered by Karl Storz Endoscopy as part of the KSEA Instrument Set for Endoscopic Surgery of Superficial Veins and Fascia of the Lower Extremities.

**Predicate Device:**

The predicate device for this submission is the Karl Storz Endoscopy Telescope for use in endoscopic surgery of superficial veins and fascia of the lower extremities.

**Summary of Device Function:**

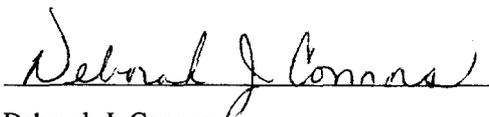
The Smith & Nephew Images 5mm x 300mm Endoscope transfers light to the surgical site via glass fiber optics and allows visualization of the surgical site through a series of optical lenses and prisms. The length of the endoscope allows it to gain access to the surgical site.

**Intended Use of Device:**

The 5mm x 300mm Images Endoscope is indicated for use in endoscopic surgery of superficial vessels and fascia of the lower extremities to provide illumination and visualization of the surgical site during decision, ligation and harvesting of vessels.

**Comparison of Technological Characteristics of Predicate Device:**

The basic technologies, design and function of the Smith & Nephew Images 5mm x 300mm Endoscope is substantially equivalent in materials, design and function to the Karl Storz Endoscopy 5mm x 300mm Telescope for use in endoscopic surgery of superficial veins and fascia of the lower extremities and raises no new issues of safety and effectiveness.



Deborah J. Connors  
Regulatory Affairs Specialist



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

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

AUG 12 1997

Re: K971850  
Trade Name: Images Endoscopes and Accessories  
Regulatory Class: II  
Product Code: GCJ  
Dated: May 19, 1997  
Received: May 20, 1997

Dear Ms. Connors:

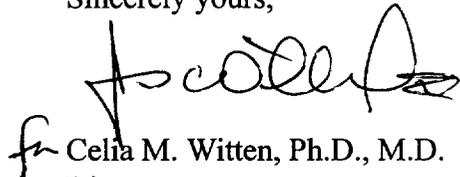
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 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 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 device in the Federal Register. Please note: this response to your premarket notification submission 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 device as described in your 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 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 device, 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,

A handwritten signature in black ink, appearing to read "Celia M. Witten". The signature is written in a cursive style with a large initial "C" and "W".

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 : K971850

Device Name : Smith & Nephew, Inc., Endoscopy Division Images Endoscopes

Indications for Use :

The 5mm x 300mm Images Endoscope (REF. 7205XXX) is indicated for use in endoscopic surgery of superficial vessels and fascia of the lower extremities to provide illumination and visualization of the surgical site during decision, ligation and harvesting of vessels.

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

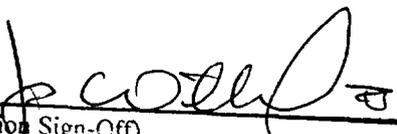
\_\_\_\_\_

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use  \_\_\_\_\_  
(Per 21 CFR 801.109)

OR Over-the-Counter \_\_\_\_\_

(Optional Format 1-2-96)

  
\_\_\_\_\_  
(Division Sign-Off)  
Division of General Restorative Devices  
510(k) Number K971850