DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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JUL 27 2015

Smith & Nephew, Inc.
Endoscopy Division
Janice Haselton
Regulatory Affairs Specialist
160 Dascomb Road
Andover, MA 01810

Re: K012724
Trade/Device Name: Smith & Nephew Vascular VideoEndoscope
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: LYK, FET
Dated (Date on orig SE ltr): August 14, 2001
Received (Date on orig SE ltr): August 14, 2001

Dear Ms. Haselton,

This letter corrects our substantially equivalent letter of November 8, 2001.

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

NOV 0 8 2001

510(k) Number: K012724

Device Name : Smith & Nephew Vascular VideoEndoscope

Indications for Use :

The Smith & Nephew Vascular VideoEndoscope is indicated for use in subcutanous endoscopy, specifically for endocopically gaining access to, ligating and/or harvesting vessels within the subcutaneous and subfascial surgical planes in the lower extremities.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter ____
(Per 21 CFR 801.109)
(Optional Format 1-2-96)

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

510(k) Number K012724

K012724

NOV 0 8 2001

Endoscopy Division

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Smith+Nephew

510(k) Summary
Smith & Nephew Vascular VideoEndoscope
Date Prepared:

This 510(k) summary is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

A. Submitter

Smith & Nephew, Inc.
Endoscopy Division
160 Dascomb Road
Andover, MA 01810

B. Company Contact

Janice Haselton
Regulatory Affairs Specialist

C. Device Name

Trade Name: Smith & Nephew Vascular VideoEndoscope
Common Name: Vascular Endoscope
Classification Name: Endoscope and/or Accessories

D. Predicate Devices

Olympus Endoscopic System for Vessel Harvesting K963184
Ethicon's EndoPath Ultra Retractor and Vessel Dissector K973139
Smith & Nephew's Images Endoscopes K971850

E. Description of Device

The proposed Smith & Nephew Vascular VideoEndoscope is designed in an "L" shaped configuration as to have the horizontal optical train and working channel as the part that is introduced into the leg and the vertical shaft as a handle. The connecting cables and tubing are conveniently located far from the leg to minimize any interference with the surgeon's hand movements. The function of the Smith & Nephew

K012724

Vascular VideoEndoscope is to create and maintain a subfascially working space, provide visualization of the working space, and provide access to hand instruments to the working space.

The attachments utilize the same locking feature located on the endoscope which allows the Smith & Nephew Vascular VideoEndoscope to be used as a multi-purpose device.

F. Intended Use

The Smith & Nephew Vascular VideoEndoscope is indicated for use in subcutanous endoscopy, specifically for endocopically gaining access to, ligating and/or harvesting vessels within the subcutaneous and subfascial surgical planes in the lower extremities.

G. Comparison of Technological Characteristics

The Smith & Nephew Vascular VideoEndoscope is substantially equivalent in design, materials of construction and function and intended use as to the Olympus Endoscopic System for Vessel Harvesting, Smith & Nephew's Images Endoscopes, and Ethicon's EndoPath Ultra Retractor and Vessel Dissector.

Janice Haselton

Regulatory Affairs Specialist