JAN 20 2000

K994084

Endoscopy Division

Smith & Nephew, Inc.
160 Dascomb Road, Andover, MA 01810 U.S.A.
Telephone: 978-749-1000
Telefax: 978-749-1599

Smith+Nephew

510(k) Summary
Smith & Nephew Light Sources And Accessories
Date Prepared: 12/01/99

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, Massachusetts 01810

B. Company Contact

Janice Haselton
Regulatory Affairs Specialist

C. Device Name

Trade Name:	Smith & Nephew Light Sources and Accessories
Common Name:	Light Sources and Accessories
Classification Name:	Fiberoptic Illuminator, 21 CFR 876.1500

D. Predicate Devices

The predicate devices for this submission are the existing line of Smith & Nephew Xenon Light Sources, Light Guides and accessories.

Description of Device

Smith & Nephew Light Sources, Light Guides and accessories are designed to transmit light to the surgical site via fiberoptic bundles in the light guide. The light guides mate to the Subcutaneous Illuminator and Light Source with instrument specific adapters.

E. Intended Use

Smith & Nephew Light Sources, light guides and accessories are indicated for use with the Subcutaneous Illuminator for the purpose of providing transillumination during endoscopic resection of superficial varicosities of the lower extremities.

F. Comparison of Technological Characteristics

The basic design and function of the Smith & Nephew Light Sources and Accessories are unchanged compared to information provided in previous submissions.

Janice Haselton
Regulatory Affairs Specialist

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 20 2000

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

Re: K994084
Trade Name: Smith & Nephew Xenon Light Source and Accessories
Regulatory Class: II
Product Code: FFS
Dated: December 2, 1999
Received: December 3, 1999

Dear Ms. Haselton:

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 requirement, 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,

for James E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K994084

510(k) Number :

Device Name : Smith & Nephew, Light Sources and Accessories

Indications for Use :

Smith & Nephew Light Sources, light guides and accessories are indicated for use with the Subcutaneous Illuminator for the purpose of providing transillumination during endoscopic resection of superficial varicosities of the lower extremities.

(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 K994084

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

(Optional Format 1-2-96)