JUL - 6 1999

K991323

Endoscopy Division

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

Smith+Nephew

April 15, 1999
510(k) Summary
Subcutaneous Illuminator

Substantial Equivalence:

The Smith & Nephew Subcutaneous Illuminator is substantially equivalent in design, materials, function, and intended use to the Dyonics Endoscope for Endoscopic Surgery of Superficial Veins and Fascia of the Lower Extremities, the Strykeflow Suction Irrigator Gravity Flow marketed by Stryker Endoscopy(K963646), the Endolumina Transillumination System II marketed by BioEnterics (K964561) and the AMD Fiberoptic End Irrigating Endo-Illuminator (K970882).

Predicate Devices:

The predicate devices for this submission are the Dyonics Endoscope for Endoscopic Surgery of Superficial Veins and Fascia of the Lower Extremities, the Stryker Strykeflow Suction Irrigator Gravity Flow, the Endolumina Transillumination System II marketed by and the AMD Fiberoptic End Irrigating Endo-Illuminator.

Summary of Device Function:

The Smith & Nephew Subcutaneous Illuminator transfers light to the surgical site via glass fiber optics and includes irrigation via an irrigation channel. The length of the Subcutaneous Illuminator allows it to gain access to the surgical site.

Intended Use of Device:

The Subcutaneous Illuminator is indicated for transillumination and irrigation during endoscopic resection of superficial varicosities of the lower extremities.

Comparison of Technological Characteristics of Predicate Device:

The basic technologies, design and function of the Smith & Nephew Subcutaneous Illuminator is substantially equivalent in materials, design and function with the exception of optical transmission capabilities, to the Dyonics Endoscopes, for use in endoscopic surgery of superficial vessels of the lower extremities and raises no new issues of safety and effectiveness. The Subcutaneous Illuminator and the EndoIllumina II Transillumination System are both intended to be inserted into the subcutaneous tissues through surgically created pockets. The Subcutaneous Illuminator and the Dyonics Endoscope are both indicated for use in endoscopic surgery of superficial vessels of the lower extremities. The Subcutaneous Illuminator, and the Strykeflow Suction Irrigator Gravity Flow are all indicated for irrigation during laparoscopic surgery. Although the AMD Fiberoptic End Irrigating Endo-Illuminator is indicated for ophthalmic use, the technology of the device is identical to the Subcutaneous Illuminator in that they are both consist of a handpiece with fiberoptic fibers and irrigation channel for illumination and irrigation of the surgical site.

Deborah J. Connors

Deborah J. Connors
Principal Regulatory Affairs Specialist

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 6 1999

Ms. Deborah J. Connors
Principal Regulatory Affairs Specialist
Smith & Nephew, Inc.
Endoscopy Division
160 Dascomb Road
Andover, MA 01801

Re: K991323
Subcutaneous Illuminator
Dated: April 15, 1999
Received: April 19, 1999
Regulatory Class: II
21 CFR §876.1500 and §880.6960
Product Code: 78 FFS and 80 GCJ

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 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). 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) 594-4613. 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/dsma/dsmamain.html".

Sincerely yours,

CAPT Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number : K 991323

Device Name : Smith & Nephew, Inc., Endoscopy Division Subcutaneous Illuminator

Indications for Use :

The Subcutaneous Illuminator is intended to be used for transillumination and irrigation 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)

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

(Optional Format 1-2-96)

David G. Segura
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K991323