K973286

ENT Division

Smith & Nephew, Inc.
2925 Appling Rd., Bartlett, TN 38133 U.S.A.
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For orders and order inquiries: 1-800-238-7538

Smith+Nephew

510(k) Summary of Safety and Effectiveness

SEP 29 1997

Trade Name:	ENTire™ Irrigating Pump
Common Name:	Electrical Irrigating Pump **Accessory to the Ear, Nose and Throat Electric Surgical Drill**
Classification Name:	Ear, nose and throat electric or pneumatic surgical drill (§ 874.4250)
Official Contact:	Deborah Arthur Group Manager Regulatory & Quality Assurance Smith & Nephew, INC. ENT Division 2925 Appling Road Bartlett, TN 38133
Telephone:	(901) 373-0200
Telefax:	(901) 373-0242
Date Prepared:	August 29, 1997

The *ENTire Irrigating Pump* is substantially equivalent to the Essential Shaver System, the XPS Irrigator Pump and the Endo-Scrub Lens Cleaning System.

The *ENTire Irrigating Pump* is an accessory to the Smith & Nephew electrically powered surgical drill equipment as well as endoscopic visualization systems. It is intended to provide irrigant in conjunction with general ear, nose and throat/head & neck procedures. This modification offers the surgeon the option of irrigating the surgical site or cleansing the lens of the endoscope during otolaryngologic/otoneurologic/head & neck/ endoscopic procedures.

The power instrumentation technology utilized in the system is equivalent to existing marketed devices. Power modality, intended use, and the mode of operation are substantially equivalent. The *ENTire Irrigating Pump* is designed to meet UL 2601-1, IEC 601-1-2 and CSA 22.2 No. 601-1.

Differences between the *ENTire Irrigating Pump* and the predicate devices should not affect the safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Deborah A. Arthur
Group Manager, Regulatory and Q. A.
Smith and Nephew, Inc.
ENT Division
2925 Appling Road
Bartlett, TN 38133

Re: K973286
ENTire™ Irrigating Pump (ENT Electric or Pneumatic Drill and Nasopharyngoscope Accessory)
Dated: August 29, 1997
Received: September 2, 1997
Regulatory Class: II
21 CFR 874.4250/Procode: 77 ERL
21 CFR 874.4760/Procode: 77 EOB

SEP 29 1997

Dear Ms. Arthur:

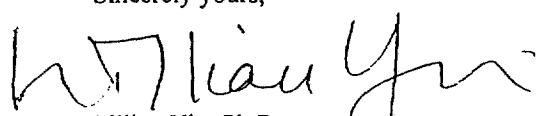
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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) 594-4613. 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/dsmamain.html".

Sincerely yours,



Lillian Yin, Ph.D.
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:
Device Name: ENTire™ Irrigating Pump
Accessory to the Ear, Nose and Throat Electrical Surgical Drill

Intended Use:

The *ENTire Irrigating Pump* is an accessory to the Smith & Nephew electrically powered surgical drill equipment as well as endoscopic visualization systems. It is intended to provide irrigant in conjunction with general ear, nose and throat/head & neck procedures.

This modification offers the surgeon the option of irrigating the surgical site or cleansing the lens of the endoscope during otolaryngologic/otoneurologic/head & neck/ endoscopic procedures.

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K973986

Prescription Use ✓
(Per 21 CFR 801.109)