K990213

ENT Division
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Smith+Nephew

FEB 2 1999

Exhibit H

510(k) Summary of Safety and Effectiveness

Trade Name:	HydraClear™ Irrigating System Modification to the ENTire™ Irrigating Pump (K973286) and Accessories to Endoscope (K932988)
Common Name:	Electrical Irrigating Pump and Accessories to Endoscopes
Classification Name:	Nasopharyngoscope (flexible or rigid) and Accessories (21 CFR 874.4760)
Official Contact:	Jeff Cobb Director R.A.\C.A.\Q.A. Smith & Nephew, INC. ENT Division 2925 Appling Road Bartlett, TN 38133
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Date Prepared:	January 21, 1999

The HydraClear System is substantially equivalent to the ENTire Irrigating Pump and the Suction/Irrigation Sheaths.

The HydraClear System is a rotary peristaltic pump and sheath assembly that provides both irrigation and cleaning.

The HydraClear Irrigating Pump's intended use is for providing both cleaning and irrigation during endosopic surgery to irrigate the surgical site and to remove blood and tissue deposits from the surface of the sinuscope lens.

The power instrumentation technology utilized in the system is equivalent to the ENTire Irrigating Pump. The HydraClear Irrigating Pump is designed to meet UL2601-1, CSA 22.2 No. 601-1, IEC 601-1, IEC 601-1, and IEC 601-1-2 requirements.

The HydraClear Sheaths, which meet the ISO 1099-1 requirements, are equivalent to the previously cleared Suction/Irrigation sheaths.

Differences between the HydraClear Irrigating Pump and Sheaths 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

FEB 2 1999

Jeff Cobb
Director, R.A.\C.A.\Q.A.
Smith & Nephew, Inc.
ENT Division
2925 Appling Road
Bartlett, TN 38133

Re: K990213
The HydraClear™ System
Dated: January 21, 1999
Received: January 22, 1999
Regulatory class: II
21 CFR 874.4760/Procode: EOB

Dear Mr. Cobb:

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

Exhibit D

Indications for Use Statement

510(k) Number:
Device Name HydraClear™ System

Indications for Use The HydraClear System is intended for endoscopic sinus surgery, to irrigate the surgical site, and for the removal of blood and tissue deposits from the surface of the sinusope lens.

David A. Segman
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K990213

Prescription Use ✓
(Per 21 CFR 801.109)