APR 14

K990414

Section 9- 510k Summary of Safety and Effectiveness

9.1 Statement	This summary of 510k safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and CFR 807.92
9.2 Submitter	Smith and Nephew Endoscopy, Inc. Endoscopy Division 130 Forbes Boulevard Mansfield, Ma. 02048
9.3 Company Contact	Amy Walters Group Manager, RA/QA/Clinical (508) 261-3776
9.4 Device Name	**Proprietary Name:** HandPort System **Common Name:** Extended Laparoscopic Device and Accessories **Classification Name:** Endoscopic accessories(78 GCJ) Laparoscopic accessories (85 HET)
9.5 Predicate Legally Marketed Device	Dexterity PneumoSleeve (K962147), cleared on July 9, 1996
9.6 Device Description	The HandPort System provides access to the abdominal cavity while maintaining pneumoperitoneum; the laparoscopic surgeon regains the tactile sense and feedback along with the increased hand-eye and instrumentation manipulation capacity of open surgery. The standard HandPort System device consists of the following components: 1. Base retractor, 2. Sleeve, 3. Bracelet, 4. Retractor Cap, with or without Instrument Portal, and 5. Sterile Lubricant

9.7 Intended Use	The Smith & Nephew HandPort System is intended to provide abdominal access to the surgeon's hand while preserving pneumoperitoneum during laparoscopic surgery. The retractor may be used independently to provide incision retraction and to protect the wound from contamination.
9.8 Device Indications	The Smith & Nephew HandPort System is indicated for use in laparoscopic procedures, where entry of the surgeon's hand may facilitate the procedure, and for extraction of large specimens.
9.9 Substantial Equivalence	**Predicate Device Comparison:** The HandPort System is substantially equivalent to the currently marketed Extended Laparoscopic Device: Dexterity PneumoSleeve. The devices are similar in materials, design, intended use, and indications for use: • Both devices are sterile, and intended for single use. • Both devices are intended to provide abdominal access to the surgeon's hand while preserving pneumoperitoneum during laparoscopic surgery. • With both devices, the retractor may also be used independently to provide incision retraction and to protect the wound from contamination during both laparoscopic and open surgery. **Testing Summary:** Bench testing confirmed that the HandPort System reliably maintains pneumoperitoneum under simulated use conditions. Simulated use testing in an animal series confirmed that the HandPort System provides sufficient hand access to anatomical structures while maintaining pneumoperitoneum for the duration of the surgical procedure. A prospective, multicenter clinical trial confirmed the capability of the HandPort System in facilitating hand-assisted surgery in a range of surgical procedures.

Applicant Amy Walters

Date 3/29/99

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 14 1999

Ms. Amy L. Walters
Group Manager, Regulatory Affairs, Quality Assurance
and Clinical
Smith & Nephew, Inc.
Endoscopy Division
130 Forbes Boulevard
Mansfield, Massachusetts 02048

Re: K990414
Trade Name: Smith & Nephew HandPort System
Regulatory Class: II
Product Code: GCJ
Dated: February 5, 1999
Received: February 10, 1999

Dear Ms. Walter:

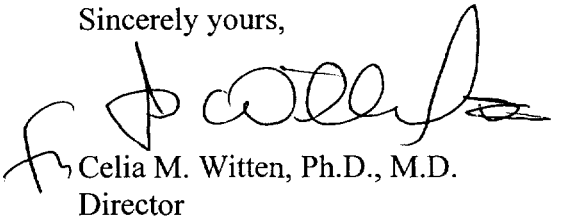
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of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



Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510 (k) Number (If Known): K990414

Device Name: Smith & Nephew HandPort System

Indications For Use:

The Smith & Nephew HandPort System is indicated for use in laparoscopic procedures, where entry of the surgeon's hand may facilitate the procedure, and for extraction of large specimens.

Intended Use:
The Smith & Nephew HandPort System is intended to provide abdominal access to the surgeon's hand while preserving pneumoperitoneum during laparoscopic surgery. The retractor may also be used independently to provide incision retraction and to protect the wound from contamination.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ or Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K990414