

Section 5- 510k Summary of Safety and Effectiveness

12974592

5.1 Statement This summary of 510k safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and CFR 807.92

5.2 Submitter Smith and Nephew, Inc.
130 Forbes Boulevard
Mansfield, Ma. 02048

5.3 Company Contact Susan Finneran
Clinical/ Regulatory Affairs
(508) 261-3772

5.4 Device Name **Proprietary Name:** Interceptre™ Laparoscopic Instruments
Common Name: Minimally Invasive Surgical Instruments: graspers, dissectors, scissors,
Classification Name: Endoscopic accessories(78 GCJ)
Laparoscopic accessories (85 HET)
Electrosurgical accessories (79 BWA, 78 KNS)

5.5 Predicate Legally Marketed Devices • Karl Storz Take-Apart Endoscopic Instruments
• Richard Wolf Laparoscopic Instruments

5.6 Device Description The Interceptre™ Endoscopic instruments are a line of hand-held , non-sterile, reusable instruments

5.7 Intended Use The Interceptre™ Endoscopic Instrumentation is intended to be used for the management of soft tissue. The instruments are intended to be used to grasp, dissect, and cut soft tissue.

5.8 Device Indications The Interceptre™ Endoscopic Instrumentation is indicated for use in endoscopic procedures.

5.9 Substantial Equivalence The Interceptre™ Endoscopic Instrumentation is substantially equivalent to the Karl Storz Take-Apart Endoscopic Instruments and the Richard Wolf Laparoscopic Instruments.
The table below summarizes the similarities of the three product lines. The similarities between the Interceptre™ Endoscopic Instrumentation and the instruments in the other two product lines support the claim of substantial equivalence.

TABLE OF SUBSTANTIAL EQUIVALENCE

Product Name	Interceptre MIS II Endoscopic Instruments	Karl Storz Take-Apart Endoscopic Instruments	Richard Wolf Laparoscopic Instruments	Smith Nephew Endoscopic Instruments
Product Labeling	non-sterile/reusable	non-sterile/reusable	non-sterile/reusable	non-sterile reusable
Materials	Stainless steel/Kynar insulation	Stainless steel/ insulation	Stainless steel/ plastic/insulation	Stainless Steel/Kynar insulation
Indications	Endoscopic Surgical Procedures	Endoscopic Surgical Procedures	Endoscopic Surgical Procedures	Endoscopic Surgical Procedures
Intended Use	Management of Soft Tissue	Management of Soft Tissue	Management of Soft Tissue	Management of Soft Tissue
Tip Styles	graspers, dissectors, scissors	graspers, dissectors, scissors	graspers, dissectors, scissors	graspers, scissors, dissectors
Number of separate components	3	3	3	1
Design	Dual / single action jaw design with 360 degree rotation	Dual / single action jaw design with 360 degree rotation	Dual / single action jaw design with 360 degree rotation	Dual / single action jaw design

Applicant *Dus Jenn*

Date *12/8/97*



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 12 1998

Ms. Susan A. Finneran
Clinical/Regulatory Affairs
Smith & Nephew, Incorporated
Endoscopy Division
130 Forbes Boulevard
Mansfield, Massachusetts 02048

Re: K974592
Trade Name: Interceptre Laparoscopic Instruments
Regulatory Class: II
Product Code: GCJ
Dated: December 8, 1997
Received: December 9, 1997

Dear Ms. Finneran:

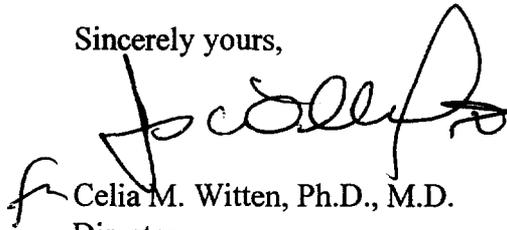
We have reviewed your Section 510(k) notification of intent to market the devices referenced above and we have determined the devices are substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date 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 devices, 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 devices are classified (see above) into either class II (Special Controls) or class III (Premarket Approval), they may be subject to such additional controls. Existing major regulations affecting your devices 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. In addition, FDA may publish further announcements concerning your devices in the Federal Register. Please note: this response to your premarket notification submissions 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 devices as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your devices to a legally marketed predicate device results in a classification for your devices and thus, permits your devices to proceed to the market.

If you desire specific advice for your devices 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 devices, 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,

A handwritten signature in black ink, appearing to read "Celia M. Witten". The signature is fluid and cursive, with a large initial "C" and "W".

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):

Device Name: Interceptre™ ^{LAPAROSCOPIC} Endoscopic Instruments

Indications For Use:

The Interceptre™ Endoscopic Instruments are indicated for use in endoscopic/laparoscopic procedures

Intended Use:

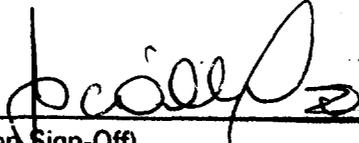
The Interceptre™ Endoscopic Instruments are a family of graspers, dissectors, and scissors which are intended to be used to grasp, manipulate, cut, cauterize soft tissue.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
 (Per 21 CFR 801.109)

or Over-The-Counter Use



(Division Sign-Off)

Division of General Restorative Devices

510(k) Number _____

K974592