

APR 23 1997

Section 8- 510k Summary of Safety and Effectiveness

K 970949

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

8.2 Submitter Smith and Nephew Endoscopy, Inc.
Endoscopy Division
130 Forbes Boulevard
Mansfield, Ma. 02048

8.3 Company Contact Amy Walters
Clinical/ Regulatory Manager
(508) 261-3774

8.4 Device Name **Proprietary Name:** Smith & Nephew MIS 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)

8.5 Predicate Legally Marketed Devices

- Karl Storz Take-Apart Endoscopic Instruments
- Richard Wolf Laparoscopic Instruments
- Smith & Nephew and Acufex MIS Instruments

8.6 Device Description The Smith & Nephew MIS Instruments are a line of hand-held, non-sterile, reusable instruments.

8.7 Intended Use The Smith & Nephew MIS Instruments are intended to be used in the surgical management of soft tissue. The instruments are intended to be used to grasp, dissect, and cut soft tissue.

**8.8 Device
Indications**

The Smith & Nephew MIS Instruments are indicated for use in endoscopic procedures, including thoracoscopic surgery and laparoscopic procedures.

**8.9
Substantial
Equivalence**

The Smith & Nephew MIS Instruments are 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 in design, materials, intended use, and indications for use between the Smith & Nephew MIS Instruments and the predicate devices support the claim of substantial equivalence.

	Smith & Nephew MIS Instruments	Karl Storz Take-Apart Endoscopic Instruments	Richard Wolf Laparoscopic Instruments	Smith Nephew & Acufex 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 Amy L Waters

Date 3/7/97