

MAR 18 1997

Section 7- 510k Summary of Safety and Effectiveness

7.1 Statement	This summary of 510k safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and CFR 807.92
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7.2 Submitter	Smith & Nephew, Inc., Endoscopy Division 130 Forbes Boulevard Mansfield, Ma. 02048
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7.3 Company Contact	Susan Finneran Clinical/ Regulatory Affairs (508) 261-3772
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7.4 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)
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7.5 Predicate Legally Marketed Devices	<ul style="list-style-type: none"> • Karl Storz Take-Apart Endoscopic Instruments • Richard Wolf Laparoscopic Instruments • Smith and Nephew Endoscopic Instruments
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7.6 Device Description	The Interceptre™ Endoscopic instruments are a line of hand-held, non-sterile, reusable instruments
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7.7 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.
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