

APR 21 1997

Section 6: 510(k) Summary of Safety and Effectiveness

K970416

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

6.2 Submitter Smith & Nephew, Inc., Endoscopy Division
130 Forbes Blvd.
Mansfield, Ma. 02048

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

6.4 Device Name Proprietary Name: Acufex Double Armed Suture Needle
Common Name: Suture Needle
Classification Name: Nonabsorbable polyester surgical suture

6.5 Predicate Legally Marketed Devices Fast Pass Suture Needle (K961853)
Smith and Nephew Endoscopy, Inc.
Mansfield, Ma.

6.6 Device Description The Acufex Double Armed Suture Needle is a sterile, single-use device manufactured from braided polyester and stainless steel.

6.7

Intended Use The Acufex Double Armed Suture Needle is intended to be used to pass a suture through soft tissue which is need of repair. The Acufex Double Armed Suture Needle is intended to be used only with the Fast Pass Suture Punch.

6.8

Device Indications The Acufex Double Armed Suture Needle is indicated for use in open or arthroscopic Rotator Cuff and Bankart repairs.

6.9

Substantial Equivalence The Acufex Double Armed Suture Needle is substantially equivalent to the recently cleared Fast Pass Suture Needle. (K961853)

Table of Substantial Equivalence

Product Name	Fast Pass Suture Needle	Acufex Double Armed Suture Needle
Product Labeling	Sterile (EtO), Single Use	Sterile (EtO), Single Use
Materials	polyester/stainless steel	polyester/stainless steel
Intended use	Soft tissue fixation	Soft tissue fixation
Indications	Arthroscopic and open shoulder lesion repair	Arthroscopic and open shoulder lesion repair
Sterilization Method	Ethylene Oxide	Ethylene Oxide

Applicant *Aus. A. Jann*

Date *1/31/97*