K964935

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Section 8: 510(k) Summary of Safety and Effectiveness

8.1 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.
8.2 Submitter	Smith and Nephew Endoscopy, Inc. 130 Forbes Blvd. Mansfield, Ma. 02048
8.3 Company Contact	Susan Finneran Clinical/Regulatory Affairs (508) 261-3772
8.4 Device Name	Proprietary Name: Suture-Lock Common Name: Suture Retention Device/ Accessory to Suture Classification Name: Suture Retention Device
8.5 Predicate Legally Marketed Devices	T-Fix Suture Bar Smith and Nephew Endoscopy, Inc. Mansfield, Ma.
8.6 Device Description	The Suture Lock is a sterile, single-use device manufactured from polyacetal.

8.7
Intended Use

The Suture Lock is intended to be use to secure soft tissue to bone, by securing the placement of sutures used in surgical procedures.

8.8
Device Indications

The Suture Lock is indicated for use in Bankart and Rotator Cuff Repair procedures.

8.9
Substantial Equivalence

The Suture Lock is substantially equivalent to the T-Fix Suture Bar which is currently manufactured and distributed by Smith and Nephew Endoscopy, Inc. (Mansfield, Ma.)
The table following summarizes the common features of the T-Fix suture Bar and the Suture Lock.

Table 4: Substantial Equivalence

Product Name	Suture Lock	T-Fix
Product Labeling	Sterile (EtO), Single Use	Sterile (EtO), Single Use
Materials	Polyacetal	Polyacetal
Intended use	Soft tissue fixation by securing suture	Soft tissue fixation by securing suture
Indications	Arthroscopic and open shoulder lesion repair	Arthroscopic and open shoulder lesion repair

Applicant Susan Finn Date 12/9/96