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K 961649

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is : _____

This summary was prepared on April 26, 1996

A. Submitter

Smith & Nephew Endoscopy
130 Forbes Boulevard
Mansfield, MA 02048

B. Company Contact

Tedd Gosian
Clinical Regulatory Manager

C. Device Name

Trade Name:	Acufex® Tibial Anchor Screw & Spiked Washer
Common Name:	Fixation Screw & Washer
Classification Name:	Single/Multiple component metallic bone fixation appliances and accessories

D. Predicate/Legally Marketed Devices

Concept® Soft Tissue Anchoring Implants (K871037)
Synthes® Spiked Washer

E. Device Description

Acufex® Tibial Anchor Screw & Spiked Washer is a device used in soft tissue to bone fixation. The Tibial Anchor Screw is a two part screw. The outer larger part has cancellous threads, which come in direct contact with bone, and is 9 mm in diameter with a length of 20 - 30 mm. The inner part, 7 mm diameter and 20 - 25 mm length, is used to attach the Spiked Washer directly to the outer part. The spiked washer is 14 - 20 mm in diameter with spikes set at the periphery.

F. Intended Use

The Acufex® Tibial Anchor Screw & Spiked Washer is indicated for fixation of soft tissue, such as tendon and ligaments, to bone in orthopedic procedures.

G. Substantial Equivalence

The Acufex® Tibial Anchor Screw & Spiked Washer is intended for use for fixation of soft tissue, such as tendon and ligaments, to bone in orthopedic procedures. The Acufex® Tibial Anchor Screw & Spiked Washer is similar in design, function, materials and intended use to other devices currently marketed and in commercial distribution, namely Concept® Soft Tissue Anchoring Implants (K871037) and Synthes® Spiked Washer.

Risks to health have been addressed through the specified materials, processing controls, quality assurance, and compliance to the Medical Device Good Manufacturing Practices regulations.

A summary comparison of the characteristics of the Acufex® Tibial Anchor Screw & Spiked Washer and the substantially equivalent device is presented in the table below.

Attribute ↓	Current Product	Substantially Equivalent Product	
	Acufex® Tibial Anchor Screw & Spiked Washer	Concept® Soft Tissue Anchoring Implants	Synthes® Spiked Washer
Indication	Soft Tissue Fixation	Soft Tissue Fixation	Ligament Fixation
Length	Outer: 20 - 30 mm Inner: 18 - 25	Screw: 25 - 55 mm	
Diameter	Outer: 9 mm. Inner: 7 mm Washer: 14 - 20 mm O.D.	Screw: 6.5 mm -. Washer: 14 to 20 mm O.D.	Washer: 13.5 mm O.D.
Materials	Screw: Titanium Washer: Titanium Reinforced Polyacetal Polymer	Screw: Titanium Washer: Titanium	Washer: Stainless Steel reinforced polyacetal
Labeling	Sterile, Single Use Only	Sterile, Single Use Only	Sterile, Single Use

Applicant Tedd R. Roman Date 4/26/96