

JUN 21 1998

K 961853

Section 7 - 510(k) Summary of Safety and Effectiveness

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

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1.2 Proprietary Name: Fast Pass Suture Punch System
Device Name: The Fast Pass Suture Punch System comprises of the following components:
Suture Punch

Suture Punch:

Proprietary Name: Fast Pass Suture Punch
Common Name: Suture Punch
Classification Name: Arthroscopic Accessory

Suture Needle:

Proprietary Name: Fast Pass Suture Needle
Common Name: Suture Needle
Classification Name: Nonabsorbable poly(ethylene terephthalate) surgical suture

Cannula/Obturator:

Proprietary Name: Fast Pass Cannula/Obturator
Common Name: Cannula, Obturator
Classification Name: Arthroscopic Accessory

These components will be offered for sale individually, and also as a system. The Fast Pass Suture Needle is a necessary component in the system. The use of other sutures or needles with the Fast Pass Suture Punch System is prohibited.

Predicate Legally Marketed Devices

Suture Punch:
Shutt Arthroscopic Suture Passer
Linvatec, Inc. (Largo, Fl.)

Suture Needle:
Ti-Cron Sutures (Davis & Geck., N83-509)
Surgical Specialties Braided Polyester Suture (N85-378)
Deknatel Silky II Polydek (P810028)

Device Indications The Fast Pass Suture Punch System is indicated for the placement of sutures in Rotator Cuff and Bankart repair procedures.

Intended Use The Fast Pass Suture Punch System is intended to be used for the placement of sutures during arthroscopic and open procedures.

Substantial Equivalence The Fast Pass Suture Punch System comprises three components: the Fast pass Suture Punch, the Fast Pass Suture Needle, and the Fast Pass Cannula/Obturator. The Fast Pass Suture Punch is substantially equivalent to the Shutt Arthroscopic Suture Passer (Linvatec, Inc. Largo, Fl.) The Fast Pass Suture Needle is substantially equivalent to Ti-Cron Sutures (Davis & Geck., N83-509), Surgical Specialties Braided Polyester Suture (N85-378), and Deknatel Silky II Polydek(P810028). The Fast Pass Cannula/Obturator is exempt from premarket notification.

Testing has shown the suitability of the Fast Pass Suture Punch System for its intended use and environment; the suture punch and suture needle successfully passed suture through a simulated tissue model.

A summary of the features of the Fast Pass Suture Punch and the substantially equivalent product is presented on the following page:

Table of Substantial Equivalent Device Similarities		
	Subject Device System	Predicate Device(s)
Product Name	Fast Pass Suture Punch System	Suture Punch: Shutt Suture Punch Suture Needle: Ti-Cron Suture Deknatel Silky Polydek Surgical Specialties Braided Polyester Suture
Product Labeling	Non-sterile, Reusable	Non-sterile, Reusable
Materials Suture Punch Suture Needle	stainless steel USP #1,#2 polyester	stainless steel USP #1,#2 polyester
Intended Use	placement of sutures	placement of sutures
Indications Suture Punch Suture Needle	Arthroscopic shoulder lesion repair Orthopaedic soft tissue fixation	Arthroscopic shoulder lesion repair Orthopaedic soft tissue fixation

Applicant *Amey Walker*

Date 6/13/96