

K970360

**SUMMARY OF SAFETY AND EFFECTIVENESS**  
**MITEK SUTURE RETROGRADER**

MAR 10 1997

**SUBMITTER**

<b>NAME</b>	Mitek Products
<b>ADDRESS</b>	60 Glacier Drive, Westwood, MA 02090
<b>TEL #</b>	617-461-9700
<b>CONTACT</b>	Edward F. Kent Vice President Regulatory Affairs
<b>DATE</b>	January 10, 1997

**NAME OF DEVICE**

<b>CLASSIFICATION NAME</b>	SUTURE PASSER, 87HWQ
<b>COMMON NAME</b>	Instrument to retrograde suture through tissue
<b>PROPRIETARY NAME</b>	MITEK Suture Retrograder

**PREDICATE DEVICE**

Acufex suture retrograder, and  
Innovasive suture passer

**DESCRIPTION OF DEVICE**  
**FUNCTION**

The suture retrograder is used to retrograde (pass) suture through soft tissue.

**MATERIALS USED**

The handle is molded from gamma stable Lexan with the remaining materials being made from stainless steel.

**INTENDED USE**

Retrograde suture through soft tissue

**COMPARISON TO PREDICATE DEVICE(S)**

Same function, hand held suture retrograde instrument to pass or retrograde suture through tissue in either open or arthroscopic procedures.

**DESCRIPTION OF NON CLINICAL TESTS**

Bench tests were done to demonstrate performance equivalence to predicate devices on the market.