K 993261

DEC - 2 1999

510(k) Summary

Trade Name: **TALON™ Anchor Snap-Pak**

Sponsor:
Mitek Products
60 Glacier Drive
Westwood, MA 02090
Registration #1221934

Contact:
Paula E. Bulger
Regulatory Affairs Project Manager
Mitek Products
60 Glacier Drive
Westwood, MA 02090
Phone: (781) 251-2700
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Device Generic Name: Staple, Fixation, Bone

Classification: According to Section 513 of the Federal Food, Drug, and Cosmetic Act, the device classification is Class II.

Product Code: JDR (21 CFR 888.3030)

Predicate Devices: K931782 - **Mitek LS Anchor**
K962511, K982420 - **Mitek Micro Anchor**

Product Description: The device described in this 510(k) is a sterile implant used to anchor or lock suture within pre-drilled bone sites and firmly secure soft tissue to bone.

Indications for Use:
The TALON™ Anchor Snap-Pak is used for the fixation of non-absorbable braided surgical suture to bone. This product is intended for the following indications:

Hand: Repair/recosntruction of collateral ligaments, Flexor and Extension tendons at the PIP (Proximalo Interphalangeal), DIP (Distal Interphalangeal) and MCP (Metacarpal interphalangeal) joints for all digits.

Wrist: Repair/reconstruction of ligaments and tendons on the dorsal and volar aspects of the carpal bones.

Safety and Performance:
The following safety and performance data has been provided to support substantial equivalence of TALON™ Anchor Snap-Pak:

Performance testing: Pull-out force (preserved human cadaver hand and wrist)
Strength comparison (TALON vs. Mitek Micro Anchor)

Conclusion:
Based on safety and performance data, similarities in design, operating principle, materials, biocompatibility and sterilization method, the TALON™ Anchor Snap-Pak has been shown to be substantially equivalent to predicate devices under the Federal Food, Drug and Cosmetic Act.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 2 1999

Ms. Cynthia A. Sinclair
Regulatory Consultant
Mitek Products
60 Glacier Drive
Westwood, Massachusetts 02090

Re: K993261
TALON™ Anchor Snap-Pak
Regulatory Class: II
Product Codes: MBI and GAT
Dated: September 28, 1999
Received: September 29, 1999

Dear Ms. Sinclair:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

James E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K993261

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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

NRO

(Division Sign-Off)
Division of General, Restorative, and
510(k) Number K993261

Prescription Use X OR Over-the -Counter Use ____
(Per 21 CFR 801.109)