K973031

510(k) SUMMARY

NOV - 3 1997

SUBMITTED BY:

R. Thomas Grotz, M.D.
530 Bush Street, 10th Floor
San Francisco, California 94108
Telephone: (415) 398-2332
Fax: (415) 398-2614

Date Submitted: August 13, 1997

CLASSIFICATION, COMMON OR USUAL NAME, DEVICE NAME

Classification Name:	Fastener, fixation, nondegradable, soft tissue
Common/Usual Name:	Soft Tissue Anchor
Proprietary Name:	Stabilizer™ Soft Tissue Anchor, 6 mm

PREDICATE DEVICES

Stabilizer Soft Tissue Anchor, 8mm, cleared February 7, 1997 under 510(k) K964297 and the Mitek Ligament Anchor manufactured by Mitek Surgical Products, Inc [510(k) 92670].

DEVICE DESCRIPTION

The Stabilizer Soft Tissue Anchor is a 316L stainless steel implant intended for use as an attachment means for soft tissue and bone in Anterior Cruciate Ligament (ACL) repair or reconstruction. Stabilizer instruments must be used to install the Stabilizer Soft Tissue Anchor.

Stabilizer placement is accomplished by drilling an appropriately sized hole in uncompromised bone with a specifically designed drill, inserting the soft tissue anchor into the bone, expanding the stabilizer teeth of the implant to secure the anchor into bone using the anchor inserter, and optionally securing the ACL to the implanted anchor by using up to three sutures. The anchor inserter (which spreads the stabilizer teeth of the implant) also serves as a suture organizer for delivery of sutures, as may be required, to the implant site during the implantation procedure. A crimper is also included to help secure the suture of choice to the Stabilizer, and to prepare the Stabilizer for entry into the predrilled hole. If sutures are not used, use of the crimper is optional.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

R. Thomas Grotz, M.D.
530 Bush Street
10th Floor
San Francisco, California 94108

NOV - 3 1997

Re: K973031
Trade Name: 6 mm Stabilizer™ Soft Tissue Anchor
Regulatory Class: II
Product Codes: MBI and HWC
Dated: August 13, 1997
Received: August 14, 1997

Dear Dr. Grotz:

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,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): Not Known

Device Name: Stabilizer™ Soft Tissue Anchor, 6 mm

Indications for Use: The Stabilizer Soft Tissue Anchor is a stainless steel implant intended for use as an attachment means for soft tissue and bone in Anterior Cruciate Ligament (ACL) repair or reconstruction. Stabilizer instruments must be used to install the Stabilizer Soft Tissue Anchor.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K973031

Prescription Use X OR Over-The-Counter Use
(PER 21 CFR 801.109)

(Optional Format 1-2-96)