

JAN 21 1999

**510(k) Premarket Notification
Stabilizer™ Soft Tissue Anchor
for ACL Repair/Reconstruction**

R. Thomas Grotz, M.D.

- Confidential -

K984200
510(k) SUMMARY

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: November 17, 1998

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

PREDICATE DEVICES

Stabilizer Soft Tissue Anchors cleared under 510(k)'s 964927 and 973031, and Mitek Ligament Anchor manufactured by Mitek Surgical Products, Inc. [510(k) K92670].

DEVICE DESCRIPTION

The Stabilizer Soft Tissue Anchor is a titanium alloy (Ti 6Al-4V ELI Alloy for Surgical Implant Applications per ASTM F136-92) implant intended for use with or without USP Sutures as an attachment means for soft tissue and bone in Anterior Cruciate Ligament (ACL) repair or reconstruction. The Stabilizer is 8 mm in diameter. 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 three sutures. The anchor inserter (which spreads the stabilizer teeth of the implant) also serves as a suture organizer for delivery of sutures to the implant site if required during the implantation procedure.

INDICATIONS FOR USE:

The Stabilizer Soft Tissue Anchor is a titanium alloy implant intended for use with or without USP Sutures 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.

CONTRAINDICATIONS, WARNINGS, PRECAUTIONS AND COMPLICATIONS

1. Contraindications

The Stabilizer Soft Tissue Anchor is contraindicated in the presence of pathological conditions such as severe osteopenia, cystic degeneration, or comminution of bone which would compromise fixation. The Stabilizer should not be used in compromised bone or in the presence of pathological soft tissue conditions which would compromise fixation. It should also not be used in the presence of pathophysiological conditions such as infection, osteonecrosis, or bone disease. The product should not be used in patients with known allergies to titanium.

2. Warnings

2.1 The Stabilizer Soft Tissue Anchor is intended to assist in the fixation of soft tissue to bone. Each case should be carefully analyzed to assure that the anchor and suture are appropriate to support the repair/reconstruction. Excessive tension on the suture or anchor may result in suture breakage or implant pull-out from the bone. In some cases, revisions may require explant of the bone anchor.

2.2 The drill is stainless steel. To assure proper bone cutting characteristics, the drill should be replaced after every 10 uses. If the drill should break during use, remnants should be removed from the surgical site prior to proceeding.

3. Precautions

The Stabilizer Soft Tissue Anchor is intended for use by surgeons familiar with soft tissue and bone attachment techniques. The patient must be cautioned against early weightbearing and/or premature ambulation as this could lead to loosening or failure of the implant or suture attachments. Standard postoperative practices for the treatment and rehabilitation of repaired joints must be followed.

4. Complications

Potential complications with the The Stabilizer Soft Tissue Anchor include, but are not limited to, the following: infection, osteomyelitis, suture breakage, implant breakage, implant pull-out, reoperation, revision or explant.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

The product design, material of construction, and function as a soft tissue anchor is substantially equivalent to the FDA cleared predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JAN 21 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K984200
Trade Name: 8mm Stabilizer Soft Tissue Anchor (Ti-alloy)
Regulatory Class: II
Product Codes: MBI and HWC
Dated: November 17, 1998
Received: November 24, 1998

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.

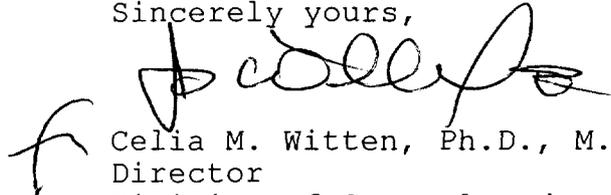
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

Page 2 - R. Thomas Grotz, M.D.

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,

A handwritten signature in black ink, appearing to read "C. Witten", is written over the typed name. To the left of the signature is a large, stylized handwritten letter "f".

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) Premarket Notification
Stabilizer™ Soft Tissue Anchor
for ACL Repair/Reconstruction

R. Thomas Grotz, M.D.

- Confidential -

Page 1 of 1

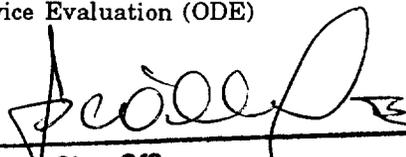
510(k) Number (if known): Not Known K734200

Device Name: Stabilizer™ Soft Tissue Anchor

Indications for Use: The Stabilizer Soft Tissue Anchor is a titanium alloy implant intended for use with or without USP Sutures 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 K984200

Prescription Use X
(PER 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)