
SUMMARY OF SAFETY AND EFFECTIVENESS

Device Name

Classification Name: Smooth or Threaded Metallic Bone Fixation Fasteners:
21 CFR §888.3040, Class II
Common and Usual Name: Suture Anchor (MAI)
Proprietary Name: Stryker XCEL Anchor System

Predicate Device

Mitek Panalok 3.5mm Absorbable Anchor System, (#K970896), currently marketed by Mitek Products/Ethicon (Westwood, MA).

Summary

This summary of 510(k) safety and effectiveness is being submitted in accordance with requirements of SMDA 1990.

The Stryker XCEL Anchor System is intended to be implanted within a pre-drilled bone hole site and provide a means for firmly securing soft tissue to bone using suture. The use of suture anchors is common in orthopedic surgery, and has been well published in professional journals such as *Arthroscopy: The Journal of Arthroscopic and Related Surgery*.

The Stryker XCEL Anchor System consists of a Poly L-lactic acid (PLLA) anchor pre-threaded with non-absorbable, braided polyester surgical suture, and pre-assembled on a disposable inserter. Stryker instrumentation, drill and soft-tissue guide/drill guide, will be used to install the Stryker XCEL Anchor.

The Stryker XCEL Anchor System will be provided pre-assembled, sterile for single-use applications (ASTM 4169). The device will be sterilized by Ethylene oxide (EN550), including limits for Ethylene Oxide residuals and validated to a sterility assurance level (SAL) of 10^{-6} . The device is biocompatible per ISO-10993 and G95-1. The Stryker XCEL Anchor is substantially equivalent in intended use, safety, and efficacy to the predicate device. The subject device was shown to have substantially equivalent performance when compared to the predicate device.

The Stryker XCEL Anchor System is considered substantially equivalent to the Mitek Panalok 3.5mm Absorbable Anchor System.

Contact:

Alisa Miller
Senior Quality Engineer
Stryker Endoscopy
5900 Optical Court
San Jose, CA 95138
(408) 754-2000 x.2259

Date: December 11, 2002



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 26 2003

Ms. Alisa Miller
Senior Quality Engineer
Stryker Endoscopy
5900 Optical Court
San Jose, California 95138

Re: K023013
Trade/Device Name: Stryker XCEL Anchor System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic fixation fastener
Regulatory Class: II
Product Code: HWC
Dated: December 11, 2002
Received: December 12, 2002

Dear Ms. Miller:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

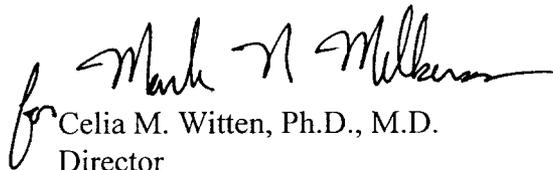
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

Handwritten signature of Celia M. Witten in black ink, appearing as 'for Celia M. Witten'.

Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative

and Neurological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

December 11, 2002

510(k) Number: K023013

INDICATION FOR USE:

The Stryker XCEL Anchor is intended for use in securing soft tissue to bone in such procedures as:

Shoulder:

Bankart repair
SI AP lesion repair
Rotator cuff repair
Capsular shift repair
Biceps tenodesis
Acromio-clavicular separation

Elbow:

Biceps tendon reattachment

Foot & Ankle:

Achilles tendon repair/reconstruction
Lateral stabilization
Medial stabilization

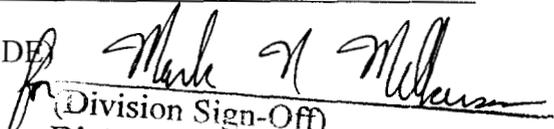
Knee:

Medial collateral ligament repair
Lateral collateral ligament repair
Joint capsule closure to anterior proximal tibia
Posterior oblique ligament or joint capsule to tibia repair
Extra capsular reconstruction/ITB tenodesis
Patellar ligament and tendon avulsion repairs

The Stryker XCEL Anchor is intended for single-use only.

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
and Neurological Devices

510(k) Number K023013

Prescription Use Yes
(Per 21 CFR 801.109)

OR

Over-the-Counter Use No