stryker® ENDOSCOPY

K027192

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MAR 2 0 2003

SUMMARY OF SAFETY AND EFFECTIVENESS

Device Name

Classification Name:	Fastener, Fixation, Biodegradable, Soft Tissue
Classification:	21 CFR §888.3040, Class II
Common and Usual Name:	Bioabsorbable Suture Anchor
Proprietary Name:	Stryker BioZip Suture Anchor

Predicate Device

Arthrex 5.0 mm Bio-Corkscrew Suture Anchor (#K990987) currently marketed by Arthrex, Inc. (Naples, FL).

Summary

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

The Stryker BioZip Suture Anchor is intended for use in reconstructive surgery to secure soft tissue to bone using suture. The suture anchor fixation technique is a common method in orthopedic surgery, and has been well published in professional journals such as *Arthroscopy: The Journal of Arthroscopic and Related Surgery.*

The Stryker BioZip Suture Anchor consists of a Poly L-lactic acid (PLLA) screw-in type suture anchor pre-threaded with two non-absorbable USP braided polyester sutures (one white and one green, needles attached) preloaded on a disposable inserter. The anchor is a bio-absorbable screw with eyelets to receive the sutures and a hex shaped cannulation down its center to accept the inserter. The inserter's hex shaped tip mates with the anchors hex shaped cannulated core. By rotating the inserter the anchor is screwed into the bone. Once in place the ends of the suture are used to secure soft tissue to the bone.

The Stryker BioZip Suture Anchor will be provided sterile for single-use (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 BioZip Suture Anchor is 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 BioZip Suture Anchor is considered substantially equivalent to the Arthrex Bio-Corkscrew Suture Anchor.

Contact:

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

Date: 01/15/03

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 0 2003

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

Re: K023192
Trade/Device Name: Stryker Biozip Suture Anchor
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HWC
Dated: January 15, 2003
Received: January 21, 2003

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.

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,

for Mark N Melkerson

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

January 15, 2003

510(k) Number: K023192

INDICATION FOR USE:

The Stryker BioZip Suture Anchor is a soft tissue anchor that will be used to secure soft tissue to bone during reconstructive surgery. The anchor is intended for use in such procedures as:

Shoulder:
Rotator Cuff Repair
Bankart Repair
SLAP Lesion Repair
Acromio-Clavicular Separation Repair
Capsular Shift/Capsulolabral Reconstruction
Biceps Tenodesis
Deltoid Repair.

Knee:
Extra Capsular Repairs
- Medial Collateral Ligament
- Lateral Collateral Ligament
- Posterior Oblique Ligament

Illiotibial Band Tenodesis
Patellar Tendon Repair.

Elbow, Wrist, Hand:
Scapholunate Ligament Reconstruction
Ulnar Collateral Ligament Reconstruction
Radial Collateral Ligament Reconstruction
Biceps Tendon Reattachment.

Foot and Ankle:
Medial Instability Repair/Reconstruction
Lateral Instability Repair/Reconstruction
Achilles Tendon Repair/Reconstruction
Midfoot Reconstruction
Hallux Valgus Reconstruction.

Pelvis: Bladder Neck Suspension Procedures.

The Stryker BioZip Suture 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)

Mark N Milhern

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K023192

Prescription Use Y-S OR Over-the-Counter Use No

(Per 21 CFR 801.109)