K983557

stryker®
ENDOSCOPY

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Todd Miller

October 8, 1998

# SUMMARY OF SAFETY AND EFFECTIVENESS

**Device Name:**

| | |
|---|---|
| Classification Name: | Smooth or Threaded Metallic Bone Fixation Fasteners: CFR 888.3040, Class II |
| Device Product Code: | Panel Code 87, Orthopedic Devices, MBI |
| Common and Usual Name: | Fastener, Fixation, Non-degradable, Soft Tissue (87MBI) |
| Proprietary Name: | Stryker Wedge Suture Anchor System |

**Regulatory Classification:** Class II

**Safety and Effectiveness Summary:**

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

Stryker Wedge Suture Anchors are titanium alloy implants used to anchor suture within bone sites for firmly securing soft tissue to bone. The Anchors are self-drilling, self-tapping, threaded devices. The Anchor is supplied with non-absorbable braided polyester suture assembled to a disposable inserter. The sutures are color-coded white and green for visual identification of the individual strands during use.

The Stryker Wedge Suture Anchor System is intended for use in securing soft tissue to bone in such procedures as rotator cuff tear repair, bankart lesion repair, and SLAP lesion repair in the shoulder, as well as achilles tendon repair in the foot/ankle, medial collateral ligament repair in the knee, scapholunate ligament reconstruction in the hand/wrist, and biceps tendon reattachment in the elbow. The Stryker Wedge Suture Anchor system is intended for the fixation of surgical suture material to the pelvis only for the purpose of bladder neck suspension female urinary incontinence due to urethral hyper mobility or intrinsic sphincter deficiency. The Stryker Wedge Suture Anchor System is equivalent in intended use, safety and effectiveness to other fixation devices in commercial distribution. The Stryker Wedge Suture Anchor System will be provided sterile for single-use applications (ASTM 4169). This device will be sterilized by Gamma irradiation and validated (AAMI ST32) to a sterility assurance level (SAL) of $10^{-6}$. The material of construction and its overall design are equivalent to currently marketed products. The device materials are biocompatible per ASTM F136 and ISO-10993.

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The anchor system does not raise any new safety and efficacy concerns when compared to other devices currently on the market. Therefore, the Stryker Wedge Suture Anchor System is substantially equivalent to other suture anchor devices.

The Stryker Wedge Suture Anchor System is substantially equivalent to the Arthrex FASTak™ Suture Anchor, marketed under 510(k) K960516, in the following fields:

- Intended use
- Material
- Geometry
- Thread design
- Head design
- Eyelet design
- Operational principles
- Indications & Contraindications

See **Table 1** and **Table 2** for comparison of anchor systems.

**TABLE 1**
**Comparison of Stryker Wedge Suture Anchor System to Arthrex FASTak Suture Anchor**

| | DEVICE UNDER REVIEW | PREDICATE DEVICE K960516 |
|---|---|---|
| **COMPANY** | Stryker | Arthrex |
| **TRADE NAME** | Stryker Wedge Suture Anchor System | Arthrex FASTak™ Suture Anchor |
| **INTENDED USE** | Soft tissue fixation to bone | Soft tissue fixation to bone |
| **MATERIAL** | Titanium (Ti 6Al 4V) | Titanium (Ti 6Al 4V) |
| **DESIGN:** | | |
| 1. Body geometry | Wedge shaped or tapered | Cylindrical then tapered |
| 2. Thread design | Spiral | Spiral |
| 3. Driving head design | Standard hexagonal | Standard hexagonal |
| 4. Suture eyelet design | Large, round, smooth | Large, round, smooth |
| 5. Diameters (mm) | 1.9 2.7 3.4 4.5 4.9 | 2.4 |
| 6. Lengths (mm) | 8 11 14 16 13.6 | 11.7 |
| **OPERATIONAL PRINCIPLES** | Provide stable fixation of soft tissue to bone; simple anchor insertion technique | Provide stable fixation of soft tissue to bone; simple anchor insertion technique |
| **INDICATIONS & CONTRAINDICATIONS** | See Users Insert (Tab B) | same |
| **STERILIZATION** | Gamma Radiation | EtO, Gamma Radiation |

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**TABLE 2**
**Comparison of Anchor Pull-out Strength in Bone**

| Company / Device | Size (mm) | Insertion | Failure Strength (lbf) | |
|---|---|---|---|---|
| Stryker Wedge Suture Anchor | 1.9 | Screw in | Diaphyseal:<br>Metaphyseal:<br>Cancellous: | 43.5 *<br>51.8<br>40.7 |
| Stryker Wedge Suture Anchor | 2.7 | Screw in | Diaphyseal:<br>Metaphyseal:<br>Cancellous: | 53.9 *<br>47.6<br>49.9 |
| Stryker Wedge Suture Anchor | 3.4 | Screw in | Diaphyseal:<br>Metaphyseal:<br>Cancellous: | 73.7 *<br>72.9<br>74.7 |
| Stryker Wedge Suture Anchor | 4.5 | Screw in | Diaphyseal:<br>Metaphyseal:<br>Cancellous: | 73.6 *<br>72.8<br>75.4 |
| Stryker Wedge Suture Anchor | 4.9 | Screw in | 18 pcf foam: | 47.6** |
| Arthrex FASTak K960516 | 2.4 | Screw in | Diaphyseal:<br>Metaphyseal:<br>Cancellous: | 38 ***<br>43<br>43 |

* Study performed by Barber and Lorang, Plano Orthopedic & Sports Medicine Center

** Testing performed using 18 pcf density foam block to simulate cancellous bone

*** Barber, M.D., "Suture Anchor Strength Revisited" *Arthroscopy: The Journal of Arthroscopic and Related Surgery, February, 1996.*

Todd Miller
Design Engineer

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 18 1998

Mr. Todd Miller
Design Engineer
Stryker Endoscopy
2590 Walsh Avenue
Santa Clara, California 95054

Re: K983557
Styker Wedge Suture Anchor System
Regulatory Class: II
Product Codes: MBI and GAT
Dated: October 8, 1998
Received: October 13, 1998

Dear Mr. Miller:

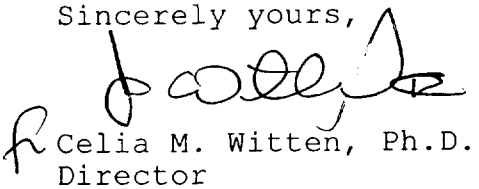
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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,



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): K983557

Device Name: Stryker Wedge Suture Anchor System

Indications For Use:

The intended use of the Stryker Wedge Suture Anchor System is for securing soft tissue to bone in such procedures as rotator cuff tear repair, bankart lesion repair, and SLAP lesion repair in the shoulder, as well as achilles tendon repair in the foot/ankle, medial collateral ligament repair in the knee, scapholunate ligament reconstruction in the hand/wrist, and biceps tendon reattachment in the elbow. The Stryker Wedge Suture Anchor system is intended for the fixation of surgical suture material to the pelvis only for the purpose of bladder neck suspension female urinary incontinence due to urethral hyper mobility or intrinsic sphincter deficiency. The suture anchor engages in bone so as to provide a stable bony attachment site for the soft tissue. This device is intended to be used primarily in arthroscopic repairs, but is suitable in open procedure as well, and is intended for single-use only. This device is intended for use only for the fixation of non-absorbable synthetic sutures.

(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 K983557

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