K071157 page 1 of 2

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stryker®

Endoscopy

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

SEP 17 2007

Date: April 2, 2007

Contact Person:

K Jeffrey Semone
Director, Regulatory Affairs
408-754-2124(phone)
408-754-2521 (fax)
jeff.semone@stryker.com

Device Name:

Proprietary Names:	Stryker PEEK Intraline Anchor
	Stryker Titanium Intraline Anchor
Common and Usual Names:	Soft Eyelet Anchor
	PEEK Soft Eyelet Anchor
	Titanium Soft Eyelet Anchor
Classification Name:	Screw, Fastener, Fixation, Nonabsorbable, Bone, Soft Tissue (Class II, 21 CFR 888.3040, Product Code MBI, Orthopedics Review Panel)

Predicate Devices:

Arthrex 5.5mm PEEK Corkscrew FT: #K061665

Device Description and Intended Use:

The Stryker Intraline Anchors are soft tissue anchors which will be used for tissue fixation to bone in the shoulder, foot/ankle, knee, hand/wrist, elbow, and pelvis. The anchors are intended for use in the following procedures:

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

Foot and Ankle:
- Lateral Stabilization
- Medial Stabilization
- Achilles Tendon Repair
- Hallux Valgus Reconstruction
- Midfoot Reconstruction
- Metatarsal Ligament Repair.

Knee:
- Anterior Cruciate Ligament Repair
- Medial Collateral Ligament Repair
- Lateral Collateral Ligament Repair
- Patellar Tendon Repair
- Posterior Oblique Ligament Repair
- Illiotibial Band Tenodesis

Hand and Wrist:
- Scapholunate Ligament Reconstruction
- Ulnar Collateral Ligament Reconstruction
- Radial Collateral Ligament Reconstruction

Elbow
- Biceps Tendon Reattachment
- Ulnar or Radial Collateral Ligament Reconstruction

Pelvis:
- Bladder Neck Suspension Procedures.

Each configuration of the Stryker Intraline Anchor Family is a screw-in anchor that is pre-threaded with non-absorbable USP braided ultra high molecular weight polyethylene (UHMWPE) suture (K033654, K040472 and K063778) and pre-assembled on a disposable inserter. The Stryker PEEK Intraline Anchor will be manufactured from PEEK-OPTIMA® (polyetheretherketone). The Stryker Titanium Intraline Anchor will be manufactured from titanium alloy Ti 6Al 4V EL1 The Stryker Intraline Anchor Family will be validated to a SAL of 10^{-6} using ethylene oxide. The EtO residuals will be tested according to ISO 10993-7.

Prior to introducing the Stryker Intraline Anchor Family to market, the devices will conform to the following voluntary safety and performance standards: ISO 10993-1, Blue Book Memorandum G95-1, EN 550, EN 556-1, EN 11607-1, EN 11607-2, EN 980, EN 1041, and EN ISO 14971.

The Stryker PEEK and Intraline Anchor is considered substantially equivalent in performance, material composition, intended use, safety, and efficacy to the Arthrex PEEK Corkscrew FT.

The Stryker Titanium Intraline Anchor is considered substantially equivalent in performance, intended use, safety, and efficacy to the Arthrex PEEK Corkscrew FT.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Stryker Endoscopy
c/o Mr. K. Jeffrey Semone
Director, Regulatory Affairs
5900 Optical Court
San Jose, CA 95138

SEP 17 2007

Re: K071157
Trade/Device Name: Stryker PEEK and Titanium Intraline Anchor
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC, JDR, MBI
Dated: August 20, 2007
Received: August 22, 2007

Dear Mr. Semone:

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 (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

Device Name: Stryker Intraline Anchor

510(k) Number if known: K071157

The Stryker Intraline Anchor is a soft tissue anchor which will be used for tissue fixation to bone in the shoulder, foot/ankle, knee, hand/wrist, elbow, and pelvis. The anchor is intended for use in the following procedures:

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

Foot and Ankle:
- Lateral Stabilization
- Medial Stabilization
- Achilles Tendon Repair
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- Midfoot Reconstruction
- Metatarsal Ligament Repair.

Knee:
- Anterior Cruciate Ligament Repair
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- Patellar Tendon Repair
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- Illiotibial Band Tenodesis

Hand and Wrist:
- Scapholunate Ligament Reconstruction
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- Radial Collateral Ligament Reconstruction

Elbow
- Biceps Tendon Reattachment
- Ulnar or Radial Collateral Ligament Reconstruction

Pelvis:
- Bladder Neck Suspension Procedures.

The Stryker Soft Eyelet RC Anchor is intended for single-use only.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use (21 CFR 801 Subpart C) No

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Buchman

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

510(k) Number K071157