

K993166



AUG 4 2000

2590 Walsh Avenue, Santa Clara, CA 95051

(408) 567-9100

SUMMARY OF SAFETY AND EFFECTIVENESS

Device Name:

Classification Name: Screw, Fixation, Bone, under 21 CFR, 888.3040

Device Product Code: 87 HWC and MAI

Common and Usual Name: Interference Screw

Proprietary Name: Stryker Bioabsorbable Interference Screw 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.

The Stryker Bioabsorbable Interference Screw System is intended for use in the surgical reconstruction of the anterior cruciate ligament (ACL) deficient knee to provide interference fixation of the various ACL allografts and autografts, including the patella bone-patellar tendon-tibial bone graft complex, the semi-tendinosus tendon graft, the semi-membranosus tendon graft, and the Achilles tendon graft. The Stryker Bioabsorbable Interference Screw System will be provided sterile for single-use applications (ASTM 4169). This device will be sterilized by Gamma irradiation (EN 552) or Ethylene oxide (EN550) and validated to a sterility assurance level (SAL) of 10^{-6} . The device is biocompatible per ISO-10993 and G95-1. The Stryker Bioabsorbable Interference Screw System is equivalent in intended use, safety and effectiveness to other fixation devices in commercial distribution. The material of construction and its overall design are equivalent to currently marketed products.

The Stryker Bioabsorbable Screw is substantially equivalent to the **Linvatec BioScrew** (510(k) K973758) in the following fields:

- Intended use
- Material
- Thread design
- Head design
- Shelf life

The Stryker Bioabsorbable Screw is substantially equivalent to the **Stryker Wedge Interference Screw (510(k) K972233)** in the following fields:

- Intended use
- Geometry
- Thread design
- Head design

Specific similarities/dissimilarities to the predicates are shown in **Table 1** and **Table 2**.

Table 1: Comparison of Stryker Bioabsorbable Interference Screw to Linvatec BioScrew and Stryker Wedge Screw

Product Name	Product Name	Intended Use	Material	Sterility	Method of Sterilization	Shelf Life
New Product Stryker	Bioabsorbable Interference Screw	Intended for use in the surgical reconstruction of the anterior cruciate ligament (ACL) deficient knee to provide interference fixation of the various ACL allografts and autografts, including the patella bone-patellar tendon-tibial bone graft complex, the semi-tendinosus tendon graft, the semi-membranosus tendon graft, and the Achilles tendon graft.	Poly(L-lactic Acid)	Sterile Single-use	Ethylene Oxide or Gamma Radiation (pending post-prototype sterilization testing)	24 months
Predicate Linvatec	BioScrew Absorbable Interference Screw (K973758)	Provide interference fixation: Patellar bone-tendon-bone grafts in ACL reconstruction Femoral and/or tibial fixation in ACL reconstruction using a soft tissue graft. PCL reconstruction	Poly(L-lactic Acid)	Sterile Single-use	Ethylene Oxide	24 months
Predicate Stryker	Wedge Interference Screw (K972233)	Intended for use in the surgical reconstruction of the anterior cruciate ligament (ACL) deficient knee to provide interference fixation of the various ACL allografts and autografts, including the patella bone-patellar tendon-tibial bone graft complex, the semi-tendinosus tendon graft, the semi-membranosus tendon graft, and the Achilles tendon graft.	Titanium (Ti 6Al 4V)	Sterile Single-use	Ethylene Oxide and Gamma Radiation	5 years

Table 2: Comparison of Stryker Bioabsorbable Interference Screw to Linvatec BioScrew and Stryker Wedge Screw

Product	Device Name	Dimensions	Head Design	Thread	Head Design	Thread Design	Thread Design
New Product Stryker	Bioabsorbable Interference Screw	Diameter: 6mm-11mm Length: 20mm-35mm	Tapered Wedge	Cannulated	Rounded Head	non-symmetric, buttress-shaped thread	spiral thread
Predicate Linvatec	BioScrew Absorbable Interference Screw (K973758)	Diameter: 7mm-11mm Length: 20mm-30mm	Cylindrical	Cannulated	Rounded Head & Fully Threaded	non-symmetric, buttress-shaped thread	spiral thread
Predicate Stryker	Wedge Interference Screw (K972233)	Diameter: 7mm-10mm Length: 20mm-35mm	Tapered Wedge	Cannulated or Solid	Rounded Head	non-symmetric, buttress-shaped thread	spiral thread

The screw system does not raise any new safety and efficacy concerns when compared to other devices currently on the market. Therefore, the Stryker Bioabsorbable Interference Screw System is substantially equivalent to other ACL fixation devices.



Todd Miller, M.S.E.
Design Engineer



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 8 2000

Mr. Todd Miller
Stryker Endoscopy Incorporated
2590 Walsh Avenue
Santa Clara, California 95051

Re: K993166
Trade Name: Stryker Bioabsorbable Interference Screw
Regulatory Class: II
Product Code: HWC, MAI
Dated: May 1, 2000
Received: May 11, 2000

Dear Mr. Miller:

This letter corrects the Indications For Use Enclosure included within our substantially equivalent letter of August 4, 2000 which incorrectly referenced your device as the "Stryker Wedge Suture Anchor System." This letter includes a corrected Indication for Use Form that correctly refers to your device as the "Stryker Bioabsorbable Interference Screw."

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 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). You may, therefore, market the device, subject to the general control provisions of the Act. The general control 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 Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General (QS) regulation (21 CFR Part 820) and that, through periodic QS inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (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 - Mr. Todd Miller

This letter will allow you to continue 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. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (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, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K993166

Device Name: Stryker Bioabsorbable Interference Screw

Indications For Use:

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Danva D. Kochmer

(Division Sign-Off)
Division of General Restor... Devices

510(k) Number K993166

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____



AUG 4 2000

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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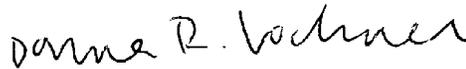
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Sincerely yours,



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Enclosure