stryker®
ENDOSCOPY

K972233

AUG - 5 1997

DISPOSABLES GROUP
Doug Lorang, M.S.E.

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# 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, HWC |
| Common and Usual Name: | ACL Interference Screw |
| Proprietary Name: | Stryker Wedge 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 Wedge Interference Screw System is intended for use in the surgical reconstruction of the anterior cruciate ligament deficient knee to provide interference fixation of the femoral and tibial bony attachments of the patella bone-patellar tendon-tibial bone graft complex, the semi-membranosus tendon grafts, and the semi-tendinosus tendon grafts, or fixation of the allograft techniques such as ACL allografts and Achilles tendon allografts. The Stryker Wedge Interference Screw System is equivalent in intended use, safety and effectiveness to other fixation devices in commercial distribution. The Stryker Wedge Interference Screw System will be provided sterile for single-use applications (ASTM 4169). This device is validated for EtO (AAMI ST27) and gamma (AAMI ST32) sterilization methods, as well as autoclave steam sterilization for re-sterilization (AAMI ST37 and SSSA), with a minimum SAL of $10^{-6}$. The material of construction (ASTM F136) and its overall design are equivalent to currently marketed products. The device material has been found to be biocompatible per ASTM F136, ISO-10993, and G95-1 standards.

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

Douglas M. Lorang, M.S.E.
Design Engineer

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Douglas M. Lorang, M.S.E.
Design Engineer
Stryker Endoscopy
2590 Walsh Avenue
Santa Clara, California 95054

AUG - 5 1997

Re: K972233
Trade Name: Stryker Wedge Interference Screw System
Regulatory Class: II
Product Code: HWC
Dated: June 12, 1997
Received: June 16, 1997

Dear Mr. Lorang:

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. Note that labeling or otherwise promoting a device for pedicular screw fixation/attachment would cause the device to be adulterated under 501(f)(1) of the Act. This device, if intended for use in pedicular screw fixation/attachment, would be found not substantially equivalent and would be a class III device under Section 513(f) of the Act. Class III devices are required to have an approved premarket approval (PMA) application prior to marketing. Accordingly:

1. The package insert must prominently state that the device is intended for the specific use(s) described in the enclosure only; and

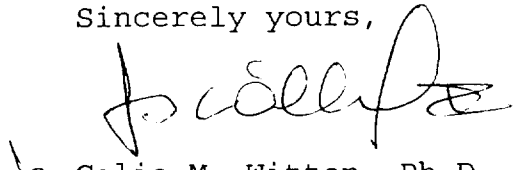
2. You may not label or in any way promote this device for pedicular screw attachment to, or fixation of the cervical, thoracic or lumbar vertebral column. If this device is a screw with outer diameters of 3 mm - 10 mm and overall lengths of 10 mm - 75 mm inclusively, the package insert must include the following statement, "**WARNING:** This device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine." Any pedicular screw fixation/attachment to the cervical, thoracic or lumbar vertebral column of this device is considered investigational and may only be investigated as a significant risk device in accordance with the investigational device exemption (IDE) regulations under 21 CFR, Part 812. All users of the device for pedicular screw fixation/attachment must receive approval from their respective institutional review boards (IRBs) and the Food and Drug Administration (FDA) prior to conduct of the investigation.

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 immediately. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and 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): K972233

Device Name: Stryker Wedge Interference Screw System

Indications For Use:

The Stryker Wedge 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 femoral and tibial bony attachments of the patella bone-patellar tendon-tibial bone graft complex, the semi-membranosus tendon grafts, and the semi-tendinosus tendon grafts, or fixation of the allograft techniques such as ACL allografts and Achilles tendon allografts.

(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 K972

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