

SEP 8 1998

10.1 510(k) Summary of Safety and Effectiveness

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K980457

Applicant Information:

Date Prepared: 1/15/98
Name: ENDO Surgical Concepts, Inc.
Address: 15 East Putnam Avenue #250
Greenwich, CT 06830
Contact Person: Alan Small
Phone Number: 203-622-8423
Fax Number 203-622-1250

Device Information:

Trade Name: ENDO Absorbable Interference Screws
Common Name: Bone or Interference Screw
Classification Name: Bone or Interference Screw

Equivalent Device:

ENDO Surgical Concepts, Greenwich, CT, Interference Screws K935836
Linvatec, Clearwater, FL Concept Absorbable Interference Screws or
Bioscrew K933719, K952831
Acufex, Mansfield, MA Interference Screws and Ligament Button and
Bioabsorbable Interference Screw K943548
Richards, Memphis, TN, Hewson Ligament Button

Intended Use:

Bone to bone fixation, fixation of bone patella bone and semitendonosus or tendon grafts in the repair of cruciate ligaments during open or arthroscopic surgery.

Summary:

The ENDO Surgical Concepts, Inc. Absorbable Interference Screws have technological characteristics that are the same as absorbable bone and interference screws currently in interstate commerce that have been registered with the Food and Drug Administration under a 510(k). The subject screws are made of absorbable polymers such as polylactic acid, polyglycolic acid, or other, or copolymers. The competitive screws are comparable in the range of sizes, screw pitch, and hex sizes. The interference screws are also comparable in terms of clinical function to metallic interference screws and ligament buttons

that have been registered under a 510(k) and used for fixation of grafts, as described in the attached articles.

The safety and effectiveness of interference screws in general is demonstrated in the reputation, clinical use, and clinical results that the surgical procedure of reconstruction of the anterior cruciate ligament with a bone patellar tendon bone graft fixed with interference screws has seen over the more than ten years of experience with its use. The high percentage of good and excellent results reported with this procedure at orthopedic meetings and in the orthopedic literature (some of which is attached to this application) has led it to be referred to as the "Gold Standard" to which comparison of new devices and procedures is made (Otero et al). In vitro mechanical testing has demonstrated the effectiveness of mechanical fixation of bone using interference screws.

Literature related to laboratory and clinical studies on interference screw fixation describe a long history of favorable results with the use of interference screws in graft fixation. The clinical article by Lambert in 1983 is the first documented use of interference screws and he described the use of the technique in 200 patients followed over 5 years. He used standard cancellous screws for fixation and found a high percentage of good to excellent results. The articles on in vitro testing document fixation strengths in the early postoperative period that are higher than other fixation methods, such as sutures in combination with a screw and washer. These forces are described as higher than the forces on the graft in the early rehabilitative period (Matthews et al, Hulstyn et al, Cassin et al). The study by Kurosaka in 1987 showed increased fixation strength with a larger diameter headless screw, compared to the standard cancellous screw, and this screw design has been used clinically since then with good results. Some effect on pullout strength was noticed by Fulkerson if the screw was inserted more than 30 degrees off axis, but a clinical paper by Lemos found the divergence to average below ten degrees. The comparison of arthroscopic versus conventional surgical technique was studied in vitro (Hecker et al, Cassin et al) and in vivo (Shelbourne et al) with similar results being attained. The clinical article by Shelbourne concluded that "similar early clinical results can be successfully achieved" with the techniques. Most of the articles have recommendations on surgical technique for optimum insertion. Other studies presented orally at local meetings have described the favorable use of interference fixation techniques.

Comparative papers from the same institution (The Hospital for Special Surgery in NY, NY) published in The Journal of Bone and Joint Surgery by O'Brien in 1991 and Buss in 1993 compare directly the use of interference screws with ligament buttons for fixation of a patellar tendon graft in anterior cruciate reconstruction surgery. In both 93 of a possible 100 points were attained on the rating scale of the Hospital for Special Surgery. The patients were followed for a minimum of two years. Sutures are used to hold the bone

plug to a ligament button, whereas with interference screws direct bone to bone apposition is attained. This clinical study documents a direct comparison of the use of interference screws with another well known method, ligament buttons, in a total of 150 patients followed for a minimum of two years.

In vitro testing has documented the initial pullout force for polylactic acid absorbable interference screw to be comparable to metallic screws with the force being well above the force expected to be applied to the construct in the immediate postoperative period. Clinical studies have shown the polylactic acid absorbable interference screw to be equivalent to metallic interference screws

ENDO Surgical Concepts, Inc. has made a reasonable search of available information about interference screws and their use in an effort to have a comprehensive background on the types of problems to which the devices are susceptible. While it is meant to be thorough such a search is necessarily limited by available resources. This search has brought to light the description in the literature in an article by L. Matthews, called "Pitfalls in the Use of Interference Screws for Anterior Cruciate Ligament Reconstruction" (article attached) of some potential problems with the use of interference screws. These include: inadvertent graft advancement, screw damage to the passing suture, and tendon laceration by screw threads. ENDO Surgical has used the product design to minimize these potential problems. The author of the article states that "an interference screw with a more tapered and less blunt tip may engage the bone plug more readily and thereby reduce risk of migration before graft engagement". The ENDO screw has a tip that is tapered to aid in the insertion process. A cannulated screw with guide wire helps to maintain alignment of the screw with the hole and the ENDO screw is used with a guide wire. In the area of screw damage to the passing suture and tendon laceration ENDO has designed the screw with thread tips that are radiused slightly broader than the competitive products to make the thread less sharp and prone to cutting. ENDO is also providing the associated cannula to cover the screw and protect the sutures and tendons from the screw during insertion. The author of the paper L. Matthews also describes some modifications of surgical techniques that can reduce the risk of these potential problems. This demonstrates that the use of the screws is effected by surgical technique.

The search also identified some MDR reports regarding device malfunctions on interference screw products manufactured by Acufex Microsurgical and Linvatech (formerly Concept, Inc.) in a search of the DIOGENES database. These reports related to the breakage or bending of the screwdrivers used to insert the interference screw and the cracking of absorbable interference screws on insertion in the hex region. The ENDO system can use a 3.5 mm hex drive, which is substantially stronger than a 2.5 mm driver due to its larger tip size. The driver shaft is also made of one piece of material, with no welds that can act

as potential sites for failure or crack initiation. The fewer than twenty MDR reports located for 1991, 1992 and 1993 compare to the annual volume use of interference screws of approximately 200,000 units in each of those years. The percentage of MDR reports for the number of devices used is approximately .003%, based on these numbers. The ENDO absorbable screw has been designed with a wall thickness and drive system that should minimize the potential problem of cracking in the drive region.

The use of interference screws in graft fixation is believed to be safe and effective based on the over ten years of clinical use with good results and mechanical testing studies supporting the biomechanical principles of interference fixation. The available MDR reports relate mostly to the insertion instruments and drive features not to the interference screws fixation thus the rate of complications of the interference screws appears to be very low. Even with this low rate ENDO has improved on these aspects of the device to try to reduce the complication rate further and learn from the experience of others. ENDO Surgical Concepts believes that the Absorbable Interference Screw System is safe and effective.

Alan Small
Pres.
ENDO Surgical Concepts, Inc.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Alan A. Small
President
ENDO Surgical Concepts, Inc.
15 East Putnam Avenue #250
Greenwich, Connecticut 06830

Re: K980457
Trade Name: ENDO Absorbable Interference Screw
Regulatory Class: II
Product Codes: HWC and MRY
Dated: June 30, 1998
Received: July 6, 1998

Dear Mr. Small:

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.

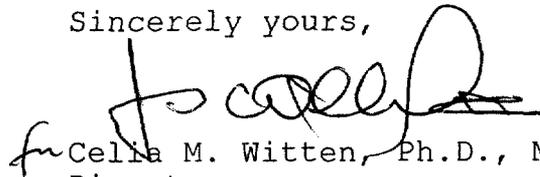
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

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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,


for Cella 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): K980457

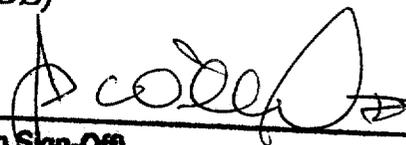
Device Name: ENDO Absorbable Interference Screw

Indications For Use:

The ENDO Absorbable Interference Screw is indicated for use in graft fixation in the repair and reconstruction of the cruciate ligaments of the knee, during open and arthroscopic surgery.

(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 K980457

cription Use X
21 CFR 801.109)

OR

Over-The-Counter Use _____