DEC 22 1998

K970829

Summary of Safety and Effectiveness Information Premarket Notification, Section 510(k)	***Phusis® Absorbable Interference Screw*** Tornier S.A.

Regulatory Authority: Safe Medical Devices Act of 1990, 21 CFR 807.92

1. **Device Name:**

   Trade Name: ***Phusis® Absorbable Interference Screw***

   Common Name: Interference Screw

   Classification Name: Screw, Fixation, Bone

2. **Establishment Name & Registration Number:**

   Name: Tornier S.A.

   Number: 8020756

3. **Classification:**

   Screw, Fixation, Bone, as categorized under 21 CFR, § 888.3040.

   § 888.3040 Smooth or threaded metallic bone fixation fastener. (a) Identification. A smooth or threaded metallic bone fixation fastener is a device intended to be implanted that consists of a stiff wire segment or rod made of alloys, such as cobalt-chromium-molybdenum and stainless steel, and that may be smooth on the outside, fully or partially threaded, straight or U-shaped; and may be either blunt pointed, sharp pointed, or have a formed, slotted head on the end. It may be used for fixation of bone fractures, for bone reconstruction, as a guide pin for insertion of other implants, or it may be implanted through the skin so that a pulling force (traction) may be applied to the skeletal system. (b) Classification. Class II.

   Device Class: Class II
   Classification Panel: Orthopaedic
   Product Code: 87HWC

4. **Company Contact:**

   Ms. Patricia Abraham, Marketing Manager
   Tornier, S.A.
   B.P. 11 - rue Doyen Gosse
   38330 - Saint Ismier
   France
   011.334.7652.8000
   011.334.7652.0673 - fax

5. **Special Controls:**

   Special Controls do not apply to this device.

6. **Substantially Equivalent Device(s):**

1. **BioScrew Fixation System.** Linvatec, Inc., K933719
2. **Acufex Screw**, Acufex Microsurgical, Inc., K895711

7. **Indications for use:**

1. Surgical repair of the anterior cruciate ligament.
2. ACL repair.
3. Arthroscopic ACL repair.

8. **Description of the Device:**

The device is a bioresorbable interference screw used for the reconstruction of the anterior cruciate ligament (ACL). The ***Phusis® Absorbable Interference Screw*** system is made up of two different diameter screws (7.0mm and 9.0mm) available in two lengths for each diameter. The 7.0mm diameter screws are 20 & 25 mm in length and the 9.0mm screws are 25 & 30 mm in length. The thread profile is that of a non aggressive single lead thread (cancellous-type) with a pitch of approximately 12 to the inch. The thread is progressive in nature. That is, the distal end or tip of the screw is tapered slightly to improve ease of insertion.

The cannulation channel serves two purposes, it allows for the insertion of a guide wire/pin and it provides the driver interface. The cannula channel is not round throughout its length, but rather, it is hex in configuration over most of its length. Only the last millimeter near the tip is round. This provides two specific benefits, maximum hex drive interface and excellent insertion orientation when inserted over the guide pine/wire.

Materials:

The material used to construct the device is described as an α -hydroxy-acid. Specifically, the material used in the construction of the ***Phusis® Absorbable Interference Screw*** is an exclusively lactic stereocopolymer containing PLA98 (98% L-lactic units and 2% D-lactic units. Resorption of PLA98 occurs exclusively by a chemical mechanism known as autocatalytic hydrolysis leading to progressive breaking of the macromolecular chains. The 2% of D-lactic units guarantee permanent hydrolysis of a PLA98 implant until its complete resorption.

Instrumentation:

Specialized instruments are provided as a part of the ***Phusis® Absorbable Interference Screw*** system. There is a cannulated hex screw driver, a non-cannulated hex screw driver, a conformator (thread tap) a clearance template and a gauge. Guide wires of the appropriate diameter are also available with the system.

9. **Claims Regarding Device Features, Performance, or Safety:**

1. Surgical technique essentially the same as for metallic interference screws.
2. Ease of use.
3. obviates the need for secondary surgery to remove the screw after healing.
4. Long history of safe use of Poly L-lactic acid material for same and similar uses.
5. strong initial and intermediate fixation followed by complete resorption.

10. Cleaning/Sterilization/Re-sterilization:

The implantable product is supplied sterile from the manufacturer. The device may not be secondarily cleaned or resterilized. Once the product packaging is opened or damaged, the product is no longer considered sterile. Inspect all packaging on arrival for evidence of shipping damage. Damaged packaging renders the product unsafe and it should not be used. Return all shipping damaged product promptly. Subsequently damaged product packaging requires product replacement. Product used in the operating room must be opened and placed into use using accepted operating room sterile technique.

The surgical instruments required to properly use the device are supplied clean only and must be sterilized prior to each use. Remove all shipping and packaging materials before sterilization. Wash all instruments thoroughly prior to sterilization. For the instruments, the recommended method is steam autoclave sterilization. The recommended sterilization cycle is based on AAMI guidelines. The cycle is saturated steam at 270° F for 30 minutes.

11. Equivalence:

Based on the materials, intended uses, design and clinical technique, the ***Phusis® Absorbable Interference Screw*** is substantially equivalent to the above referenced legally marketed **BioScrew Fixation System** available from Linvatec, Inc.

12. Feature Comparison Table:

FEATURE	Phusis Screw	BioScrew	Acufex	SE?
Indications for Use(s):	ACL reconstruction	same	same	Yes
Design:	cylindrical headless cannulated tapered cancellous thread interference screw	same	same	Yes
Sterility Assurance Level	SAL 10^{-6}	same	same	
Sterilization Method:	Hydrogen Peroxide Plasma	Gamma	Unsterile	Yes
Sizes	4	same	same	Yes
Material:	PLA98	PLA	Titanium	Yes/no
Accessory Items:	Specialized Surgical Instruments	same	same	No
Manufacturer:	Phusis	Linvatec, Inc.	Acufex Microsurgical	Yes
Product Code:	87HWC	same	same	Yes
K - Number	Pending	K933719	K895711	Yes

13. Clinical Summary:

A retrospective review and analysis of European ACL reconstruction clinical results using the Phusis screw was undertaken. The purpose of the review was to examine clinical performance of the Phusis screw and contrast it with the Linvatec BioScrew and the Acufex metallic interference screw as reported in the peer review literature. Nine common ACL clinical variables were identified and matched for comparison. Appropriate statistical methodologies were applied.

The comprehensive report detailed variables such as ***n***, average follow-up, symptoms, pivot shift, breakage of the screw on insertion, return to activity, intra-operative and post-operative complications, and final outcome was completed. The analysis supports the our conclusion that the performance of the Phusis screw is substantially equivalent to the referenced comparison devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 22 1998

Mr. David W. Schlerf
Buckman Company, Inc.
Representing Tornier S.A.
200 Gregory Lane, Suite C-100
Pleasant Hill, California 94523-3389

Re: K970829
Phusis® Absorbable Interference Screw
Regulatory Class: II
Product Codes: MAI and HWC
Dated: November 3, 1998
Received: December 7, 1998

Dear Mr. Schlerf:

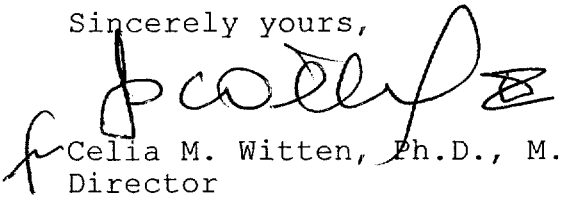
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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: **K970829**

Device Name: ***Phusis® Absorbable Interference Screw***

Intended Use:

1. **Interference fixation of patellar bone-tendon-bone grafts in ACL reconstruction.**

Specific Indications For Use:

1. **Open Surgical Reconstruction of the Anterior Cruciate Ligament (ACL)**
2. **Arthroscopic ACL Reconstruction**

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K970829

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109) (Optional format 1-2-96)