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510 (K) SUMMARY – BIO-EUROLIG® SCREW

Submitter name:	Fournitures Hospitalières Industrie
Submitter adress:	6 Rue Nobel, Z.I. de Kernevez QUIMPER, France 29000
Contact person:	C.QUENDEZ
Phone Number:	33.2.98.55.68.95
Fax Number:	33.2.98.53.42.13
Date prepared:	May 28, 2003
Device Trade Name:	BIO-EUROLIG® SCREW
Device common name:	Bioabsorbable Interference Screw
Classification name:	Bone Fixation Screw
Predicate Devices:	**BIO RCI** Smith & Nephew K 992396 **BIO Screw** Linvatec K 973758 **ARTHREX Bio-Interference Screw** Arthrex K 971358
Device description:	The Bio-Eurolig® screw is a bioabsorbable interference screw made of Poly-Lactid Acid (PLA) and available in 3 diameters (7, 8 and 9mm) and in 2 lengths (25 and 30). They are delivered sterile and are single use.
Intended use:	The Bio-Eurolig® screw is intended to provide interference fixations of bone-tendon-bone and soft tissue grafts in ACL reconstruction through arthroscopy or arthrotomy.
Device Technological Characteristics and Comparison to Predicate Characteristics and Devices:	The Bio-Eurolig® screws have the same intended use and substantial similar indications for use as the predicate devices. They are all made of the same material (PLA), are available in similar diameters and lengths. They have similar design with a rounded head. The Bio-Eurolig® and the Bio RCI screws have both a right and a left thread.

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Performance Data: Risk to health have been addressed through the specified materials, Processing controls, quality assurance and compliance to the Medical Device Good Manufacturing Practices Regulations. Testing were performed to characterize the functionality, durability and safety of the Bio-Eurolig® screws.

Conclusion: The Bio-Eurolig® Screws are substantially equivalent to predicate devices in terms of intended use, safety, and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 4 2004

Mr. M. Philippe Schweblin
President du Directoire
Fournitures Hospitaliéres Industrie
ZI de Kernevez – 6 rue Nobel
29000 Quimper
France

Re: K031939
Trade/Device Name: Bio-Eurolig® Screw
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HWC
Dated: March 25, 2004
Received: March 29, 2004

Dear Mr. Schweblin:

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 (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for 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): K031939

Device Name: BIO-EUROLIG® screw

Indications For Use:

The BIO-EUROLIG® screw is intended to provide interference fixations of bone-tendon-bone and soft tissue grafts in ACL reconstruction through arthroscopy or arthrotomy.

(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, and Neurological Devices

510(k) Number K031939

Prescription Use ✓ (Per 21 CFR 801.109) or Over-The-Counter Use No

(Optional Format 1-2-96)