K090994
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MAY - 6 2009

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

1. GENERAL INFORMATION

Trade Name	LIGAFIX® Resorbable Interference Screw ComposiTCP® Resorbable Interference Screw
Common Name	Bone Fixation Screw
Classification Name	Screw, Fixation, Bone
Class	II
Product Code	HWC
CFR section	21CFR 888.3040
Device panel	Orthopedic
Legally marketed predicate devices	LIGAFIX® INTERFERENCE SCREW (K061262 and K070507) manufactured by SCIENCE FOR BIOMATERIALS
Submitter	SCIENCE FOR BIOMATERIALS Sciences et Bio Matériaux ZI du Monge F 65100 LOURDES – FRANCE Registration Number : 3004549189
Contact	Denis CLEMENT, CEO Tel : +33 (0)5 62 42 21 01 Fax : +33 (0)5 62 42 21 00 e-mail : denis.clement@sbm-fr.com Regulatory contact: Idée Consulting (FRANCE) Isabelle DRUBAIX e-mail : idrubaix@nordnet.fr

2. DEVICE DESCRIPTION

LIGAFIX® / ComposiTCP® range of products consists of resorbable cannulated screws available in several models designed for the interference fixation of grafts in anterior cruciate ligament reconstruction.

LIGAFIX® / ComposiTCP® interference bone screw is made of a ceramic (beta-TCP) / polymer (Poly Lactic Acid -PLA) composite.

LIGAFIX® / ComposiTCP® interference screw is available in several sizes and in two beta-TCP/ PLA ratios 60/40 (LIGAFIX® 60/ ComposiTCP® 60) and 30/70 (LIGAFIX® 30/ ComposiTCP® 30)

LIGAFIX® / ComposiTCP® interference bone screws are supplied sterile and individually packaged in double heat sealed pouches.

3. INTENDED USE

LIGAFIX® / ComposiTCP® is a cannulated, sterile, single-use, resorbable interference bone screw made of a mixture of tri calcium phosphate (beta-TCP) and Poly Lactic Acid (PLA) designed for the interference fixation of grafts in anterior cruciate ligament reconstruction.

4. PERFORMANCE DATA

Biological, mechanical and biocompatibility tests confirmed that LIGAFIX® / ComposiTCP® screws are highly biocompatible and presents the requisite strength to provide sustained fixation of the graft. LIGAFIX®/ ComposiTCP® screws strength retention profiles are compatible with the healing process.

5. SUBSTANTIAL EQUIVALENCE

The modifications to LIGAFIX® / ComposiTCP® Interference screw (K050407, K061262 and K070507) consist of additional size of screw together with the deletion of a reference to surgical technique in the instructions for use.
The additional LIGAFIX® / ComposiTCP® Interference screws are substantially equivalent to their predicate devices LIGAFIX® / ComposiTCP® Interference screw (K050407, K061262 and K070507) in terms of intended use, material, design, mechanical properties and function.

Summary preparation date: May 5, 2009

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 6 2009

SCIENCE FOR BIOMATERIALS
% Mr. Denis Clement
CEO
ZI du Monge
F 65100 LOURDES – FRANCE

Re: K090994
Trade/Device Name: LIGAFIX® RESORBABLE INTEREFERNCE SCREW
ComposiTCP® RESORBABLE INTERFERENCE SCREW
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HWC
Dated: March 23, 2009
Received: April 7, 2009

Dear Mr. Clement :

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.

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K090994

Device Name: **LIGAFIX® RESORBABLE INTERFERENCE SCREW**
CompositCP® RESORBABLE INTERFERENCE SCREW

Indications for Use:

"LIGAFIX® interference screws are designed for the interference fixation of grafts in anterior cruciate ligament reconstruction."

Prescription Use ✓ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K090994