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AUG 12 2008

510(k) Summary
BioactIF OSTEOTRANS™
Interference Screw

Submitter's name : Takiron Co., Ltd.

Submitter's address: 3-13 Azuchi-machi 2-chome, Chuo-ku, Osaka 541-0052, Japan

Contact Person : Kunihiro Hata
Regulatory Affairs Specialist
7-1-19, Minatojimaminamimachi, Chuo-ku,
Kobe, Hyogo, 650-0047, Japan
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Date prepared: May 9, 2008

Trade or proprietary name: BioactIF OSTEOTRANS™ Interference Screw

Common or usual name: Bioabsorbable interference screw

Classification name: Bone fixation screw, Class II

Device product code: HWC - 21 CFR 888.3040 Screw, Fixation, Bone

Establishment Registration Number:

Takiron Co., Ltd. has not yet obtained an Establishment Registration Number.

Legally Marketed Predicate Devices:

1. Biocomposites Ltd.; Biosteon™ Screw (K003641)
2. Biocomposites Ltd.; BioLok® Screw (K002070)
3. Mitek Products; Mitek Biocryl Interference Screw (K013572)
4. Smith & Nephew Inc.; Smith & Nephew HAPLA Interference Screw (K002274)

Intended Use:

The BioactIF OSTEOTRANS™ Interference Screw is indicated for the fixation of bone-tendon-bone grafts or soft tissue grafts during anterior / posterior cruciate ligament reconstruction surgery.

Device Description:

The BioactIF OSTEOTRANS™ Interference Screw is a sterile, single-use interference screw manufactured from composites of hydroxyapatite and poly-L-lactide (HA/PLLA). Screws are provided with various sizes typical of other marketed fixation devices.

Summary of Technology:

The BioactIF OSTEOTRANS™ Interference Screw has the same technological characteristics (i.e., design and material) when compared to the predicate devices. Performance data demonstrate that the BioactIF OSTEOTRANS™ Interference Screw has the requisite strength and favorable degradation profile to provide sufficient and sustained fixation for intended uses.

Substantial equivalence

The BioactIF OSTEOTRANS™ Interference Screw is indicated for the same uses and anatomical regions as the predicate devices.

The BioactIF OSTEOTRANS™ Interference Screw has very similar physical design features and functional characteristics as the predicate devices.

Therefore the BioactIF OSTEOTRANS™ Interference Screw is substantially equivalent in design, materials and intended use and principles of operation to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Takiron Co., Ltd
% Mr. Kunihiro Hata
Regulatory Affairs Specialist
Medical Institute
7-1-19, Minatojimaminamimachi,
Chuo-Ku,
Kobe, Hyogo
Japan 650-0047

AUG 12 2008

Re: K081390
Trade/Device Name: BioactIF OSTEOTRANS™ Interference Screw
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HWC
Dated: May 9 2008
Received: May 19, 2008

Dear Mr. Kunihiro:

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 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 postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

INDICATIONS FOR USE

Applicant: Takiron Co., Ltd.
510(k) Number (if known): K081390
Device Name: BioactIF OSTEOTRANS™ Interference Screw

Indications For Use:

The BioactIF OSTEOTRANS™ Interference Screw is indicated for the fixation of bone-tendon-bone grafts or soft tissue grafts during anterior / posterior cruciate ligament reconstruction surgery.

Prescription Use X OR Over-The-Counter Use No
(Per 21 CFR 801.109)

(Please do not write below this line—continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Buch MD for MXM
(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K081390