K081608 1/2

Summary of Safety and Effectiveness for the Proximal Humerus Scaffold Fixation System (PHSFS)

submitted by
TOBY Orthopaedics
3773 Matheson Avenue
Miami, Florida 33133
Phone: 1 (305) 495-3115

DEC 19 2008

Contact Person: Al Weisenborn
Device Trade Name: Proximal Humerus Scaffold Fixation System (PHSFS)
Common Name: Shoulder Plate
Classification Name: Single/multiple component metallic bone fixation appliances and accessories per 21 CFR § 888.3030

Identification of a Legally Marketed Predicate Device

The TOBY Orthopaedics Proximal Humerus Scaffold Fixation System (PHSFS) is substantially equivalent to Synthes LCP Proximal Humerus Plate that is legally marketed and distributed by Synthes (USA).

Device Description

The Proximal Humerus Scaffold Fixation System (PHSFS) is intended for the repair of proximal humeral fractures. The system consists of a titanium plate, posts, cross-pegs, cortical screws, 1.5 mm K-Wires, manual surgical instruments, alignment fixture and a custom sterilization container.

Intended Use

The Proximal Humerus Scaffold Fixation System (PHSFS) is indicated for fractures and fracture dislocations, osteotomies, and non-unions of the proximal humerus.

Summary of Technological Characteristics

A 15-point comparison of technological characteristics and a 4-point comparison of performance characteristics of the TOBY Orthopaedics Proximal Humerus Scaffold Fixation System (PHSFS) and the predicate device were performed. The devices were found to be substantially equivalent.

Summary of Performance Data

The TOBY Orthopaedics Proximal Humerus Scaffold Fixation System (PHSFS) complies with the requirements of listed FDA Recognized Consensus Standards.

- ASTM F136-02a, Standard Specification for Wrought Titanium-6 Alumi-num-4 Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401))
- ASTM F899-07, Standard Specification for Stainless Steel for Surgical Instruments

The TOBY Orthopaedics Proximal Humerus Scaffold Fixation System (PHSFS) is substantially equivalent to Synthes LCP Proximal Humerus Plate that is legally marketed and distributed by Synthes (USA) This has been demonstrated through a 15-point technological comparison of features and a multi-parameter comparison of mechanical performance.

The implantable and tissue contact materials used to fabricate the Proximal Humerus Scaffold Fixation System (PHSFS) and Instruments have a long history of safe usage in medical devices. Because the TOBY Orthopaedics Proximal Humerus Scaffold Fixation System (PHSFS)s meets the requirements of the stated standards and embody technological characteristics essentially identical to the predicate device, we believe the device is safe and effective and performs as well as or better than the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 19 2008

TOBY Orthopaedics, LLC
% Mr. Al Weisenborn
3773 Matheson Avenue
Miami, Florida 33133

Re: K081608
Trade/Device Name: Proximal Humerus Scaffold Fixation System (PHSFS)
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: HRS, HWC
Dated: September 25, 2008
Received: November 28, 2008

Dear Mr. Weisenborn:

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 the 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

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510(k) Number (if known): K081608

Device Name: Proximal Humerus Scaffold Fixation System (PHSFS)

Indications for Use:

The Proximal Humerus Scaffold Fixation System (PHSFS) is indicated for fractures and fracture dislocations, osteotomies, and non-unions of the proximal humerus.

Prescription Use X
(Per 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 IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K081608

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