K081759 #12

OCT 16 2008

P.O. Box 708
Warsaw, IN 46581-0708
574 267-6131

Summary of Safety and Effectiveness

Sponsor:	Zimmer, GmbH Sulzer Allee 8 Winterthur, Switzerland CH-8404
Contact Person:	Eric S. Pittman Associate, Regulatory Affairs Telephone: (574) 371-8369 Fax: (574) 372-4605
Date:	06/20/2008
Trade Name:	*NCB*® Polyaxial Locking Plate System; Proximal Humeral Plates and *Zimmer*® Universal Locking System; 3.5mm *Tivanium*® Ti-6Al-4V Alloy Locking Screws
Common Name:	Plating System
Classification Name and Reference:	Plate, Fixation, Bone (21 CFR § 888.3030) Screw, Fixation, Bone (21 CFR § 888.3040)
Predicate Device:	*NCB* Plating System, manufactured by Zimmer GmbH, K042695, cleared October 29, 2004 *Zimmer*® Universal Locking System, manufactured by Zimmer Inc., K060710, cleared April 26, 2006
Device Description:	The *NCB* Polyaxial Locking Plate System is an extramedullary internal fixation plate system to be used for proximal humeral fractures. It is intended to be implanted either percutaneously or by a traditional open method. The *Tivanium* 3.5mm locking screws are used to engage the proximal locking screw holes within the *NCB* Polyaxial Locking Plate System, Proximal Humeral Plates.

K081759 #2/2

Intended Use:	The *NCB* Polyaxial Locking Plate System is indicated for temporary internal fixation and stabilization of fractures and osteotomies of long bones. The *Tivanium* 3.5mm Locking Screws are intended to be used with the *NCB* Polyaxial Locking Plate System.
Comparison to Predicate Device:	The *NCB* plates have the same intended use, similar performance characteristics and are similar in design and materials to the predicate device. The Universal Locking System screws have the same intended use, similar performance and design characteristics. The proposed device is made from *Tivanium* (Ti-6Al-4V) alloy versus the Stainless Steel of the predicate device.
Performance Data (Non-clinical and/or Clinical):	*Non-Clinical Performance and Conclusions:* The results of non-clinical (Laboratory / performance) testing demonstrate that the device is safe and effective. *Clinical Performance and Conclusions:* Clinical data and conclusions were not needed for this device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 1 6 2008

Zimmer, GmbH
% Zimmer, Inc.
Mr. Anthony Francalancia, RAC
P.O. Box 708
Warsaw, Indiana 46581-0708

Re: K081759
Trade/Device Name: *NCB*® Polyaxial Locking Plate System, Proximal Humeral Plates and *Zimmer*® Universal Locking System; 3.5mm *Tivanium*® Ti-6Al-4V Alloy Locking Screws
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 19, 2008
Received: September 22, 2008

Dear Mr. Francalancia:

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

510(k) Number (if known): K081759

Device Name:

NCB® Polyaxial Locking Plate System, Proximal Humeral Plates
Zimmer® Universal Locking System, 3.5mm Tivanium Ti-6AL-4V Alloy Screws

Indications for Use:

The *NCB* Polyaxial Locking Plate System is indicated for temporary internal fixation and stabilization of fractures and osteotomies of long bones.

Prescription Use _X_ AND/OR Over-The-Counter Use ____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(Please do not write below this line – Continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. O'Leary for mxm

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

510(k) Number K081759