K100111 (1/2)

APR 12 2010

P.O. Box 708
Warsaw, IN 46581-0708
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Summary of Safety and Effectiveness

Sponsors:	Zimmer, Inc. P.O. Box 708 Warsaw, IN 46581-0708 Zimmer, GmbH SulzerAllee 8 Winterthur, Switzerland CH-8404
Contact Person:	Anthony Francalancia RAC Senior Associate, Regulatory Affairs Telephone: (574) 372-4570 Fax: (574) 372-4605
Date:	April 12, 2010
Trade Name:	*NCB*® Periprosthetic Femur Polyaxial Locking Plate System
Common Name:	Locking Plate System
Classification Name and Reference:	Plate, Fixation, Bone; Screw, Fixation, Bone 21 CFR § 888.3030 and 888.3040
Predicate Devices:	4.5mm Locking Compression Plate (LCP) System with Expanded Indications, manufactured by Synthes, K082807, cleared January 13, 2009, and *NCB*® Plating System, K042695, cleared October 29, 2004.
Device Description:	The *NCB* (Non-Contact Bridging) Periprosthetic Femur Polyaxial Locking Plate System is a line of polyaxial locking plates for the treatment of femur fractures, particularly of periprosthetic femur factures. It consists primarily of Proximal Femur Plates, Distal Femur Plates, and Curved Shaft Plates. The *NCB* technology allows for polyaxial screw placement (30° cone) with screw locking achieved with the use of locking caps that are threaded into the plate holes. In the locked mode the *NCB* Periprosthetic plate acts as an internal fixator without contact between the plate and the bone

surface, reducing the risk of periosteal blood supply impairment. This Non-Contact Bridging concept can be specifically controlled through the use of 1, 2, or 3mm spacers, which are threaded into the plate holes prior to plate insertion. Plates, screws, blind screw inserts, spacers and locking caps are made of titanium alloy.

Intended Use:

The *NCB* Periprosthetic Femur Polyaxial Locking Plate System is indicated for temporary internal fixation and stabilization of fractures and osteotomies of long bones, including: Periprosthetic fractures, Comminuted fractures, Supracondylar fractures, Fractures in osteopenic bone, Nonunions, Malunions

Comparison to Predicate Devices:

The *NCB* Periprosthetic Femur Polyaxial Locking Plate System is similar in intended use, materials, sterility, and performance characteristics to the predicate devices.

Performance Data (Nonclinical and/or Clinical):

Non-Clinical Performance and Conclusions:

The results of non-clinical (lab) performance testing demonstrate that the devices are safe and effective and substantially equivalent to the predicate devices. Plate testing/analysis performed included; construct fatigue-Proximal Femur Plate, Distal Femur Plate strength, Shaft Plate strength, NCB screw/Shaft Plate compression slot interface evaluation, and construct fatigue - Proximal Femur Plate with Cable and Cable Button. System screws were tested to determine starting load, driving torque and torque to failure.
A literature review was conducted to substantiate the use of the proposed device in osteopenic bone.

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
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Zimmer, Inc.
% Mr. Anthony Francalancia
Senior Associate, Regulatory Affairs
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Warsaw, Indiana 46581-0708

APR 12 2010

Re: K100111
Trade/Device Name: NCB® Periprosthetic Femur Polyaxial Locking Plate System
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: January 12, 2010
Received: January 14, 2010

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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

Enclosure

Indications for Use

510(k) Number (if known): K100111

Device Name:

NCB® Periprosthetic Femur Polyaxial Locking Plate System

Indications for Use:

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- Periprosthetic fractures
- Comminuted fractures
- Supracondylar fractures
- Fractures in osteopenic bone
- Nonunions
- Malunions

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)

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

510(k) Number K100111