K061211

## Summary of Safety and Effectiveness

JUN 14 2006

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| **Submitter:** | Zimmer, Inc.<br>P.O. Box 708<br>Warsaw, IN 46581-0708 |
| **Contact Person:** | Anthony Francalancia<br>Senior Associate, Regulatory Affairs<br>Telephone: (574) 372-4570<br>Fax: (574) 372-4605 |
| **Date:** | April 28, 2006 |
| **Trade Name:** | *NCB*® Plating System |
| **Common Name:** | Plate, Fixation, Bone<br>Screw, Fixation, Bone |
| **Classification Reference:** | 21 CFR § 888.3030, 3040 |
| **Predicate Devices:** | Zimmer *NCB*® Plating System, Humerus and Femur Plates (K042695, cleared October 29, 2004).<br>Synthes 4.5mm Titanium LCP Proximal Tibia Plating System (K023802, cleared January 28, 2003).<br>Synthes 3.5mm Titanium LCP Proximal Tibia Plating System (K030597, cleared March 20, 2003). |
| **Device Description:** | The *NCB* Plating System is an extramedullary internal fixation plate system to be used for proximal tibia fractures. It is intended to be implanted either percutaneously or by a traditional open method. |
| **Intended Use:** | The *NCB* Plating System is indicated for temporary internal fixation and stabilization of fractures and osteotomies of long bones. |
| **Comparison to Predicate Device:** | The *NCB* Plating System Proximal Tibia plates have the same intended use, similar performance characteristics, are made of the same material and are similar in design to the predicate devices. |

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| **Performance Data (Non-clinical):** | The results of non-clinical (laboratory) performance testing demonstrate that the device is safe and effective. |

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, GmbH
% Mr. Anthony Francalancia
Senior Associate, Regulatory Affairs
P.O. Box 708
Warsaw, Indiana 46581

APR 13 2012

Re: K061211
Trade/Device Name: NCB® Plating 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: April 28, 2006
Received: May 1, 2006

Dear Mr. Francalancia:

This letter corrects our substantially equivalent letter of June 14, 2006.

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 (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 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.

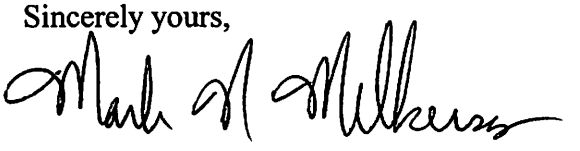
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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):** K061211

**Device Name:**

*NCB*® Plating System

**Indications for Use:**

The NCB Plating 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)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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



**510(k) Number** K061211