K042695

OCT 2 9 2004

Summary of Safety and Effectiveness

Submitter:	Zimmer, Inc. P.O. Box 708 Warsaw, IN 46581-0708
Contact Person:	Stephen H. McKelvey Manager, Corporate Regulatory Affairs Telephone: (574) 372-4944 Fax: (574) 372-4605
Date:	September 29, 2004
Trade Name:	*NCB*® Plating System
Common Name:	Plate, Fixation, Bone Screw, Fixation, Bone
Classification Reference:	21 CFR § 888.3030, 3040
Predicate Devices:	Synthes Anatomical Locking Plate System (aka LISS), K961413, cleared 8-7-96 DePuy Orthopedics Pe.R.I. II Knee Fracture System, K003235, cleared 11-06-00 Synthes LCP Proximal Humerus Plate, K011815, cleared 9-6-01.
Device Description:	The *NCB* Plating System is an extramedullary internal fixation plate system to be used for either distal femoral or proximal humeral 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 has the same intended use, similar performance characteristics, is manufactured from similar materials and is similar in design to the predicate devices.
Performance Data:	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
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 9 2004

Mr. Stephen H. McKelvey
Manager, Corporate Regulatory Affairs
Zimmer, Inc.
P.O. Box 708
Warsaw, Indiana 46581

Re: K042695
Trade/Device Name: NCB® Plating System
Regulation Number: 21 CFR 888.3030, 21 CFR 888.3040
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories, Smooth threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HRS, HWC
Dated: September 29, 2004
Received: September 30, 2004

Dear Mr. McKelvey:

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.

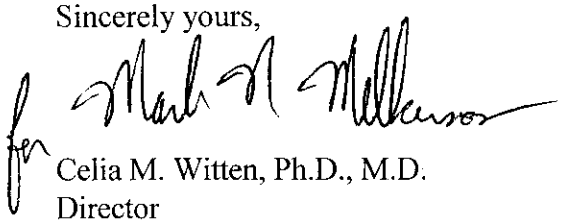
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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 Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



for Celia M. Witten, Ph.D., M.D.
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):

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)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N. Milhous
Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

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