K101696

Pg. 1/2

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

SEP 10 2010

Sponsor:	Zimmer, Inc. P.O. Box 708 Warsaw, IN 46581-0708
Contact Person:	Stephen McKelvey Senior Project Manager, Regulatory Affairs Telephone: (574) 372-4944 Fax: (574) 372-4605
Date:	September 1, 2010
Trade Name:	*MotionLoc*™ Screw for *NCB*® Polyaxial Locking Plate System
Common Name:	Bone Screw
Classification Name and Reference:	Screw, Fixation, Bone 21 CFR § 888.3040
Predicate Device:	*NCB* Plating System, K042695, cleared October 29, 2004; *NCB* Plating System, Proximal Tibial Plates, K061211, cleared June 14, 2006; *NCB* Plating System, Proximal Humeral Plates, K081759, cleared October 16, 2008.
Device Description:	The *MotionLoc* Screw for Polyaxial *NCB* Locking Plate System is used in conjunction with the *NCB* Polyaxial Locking Plate System. It is a member of the *NCB* Screw family and is used as an alternative for standard *NCB* Screws in applications where a surgeon desires reduced stiffness in a construct. The *MotionLoc* Screw for Polyaxial *NCB* Locking Plate System has a standard *NCB* Screw front thread section, a mid-section with a reduced core-diameter, a collar region, and a standard *NCB* Screw head for engagement in *NCB* locking plates. The *MotionLoc* Screws provide unicortical fixation in the far cortex of a diaphysis and are locked into the plate, without being rigidly fixed in the near cortex underlying the plate.

The *NCB* technology allows for polyaxial screw placement (30° cone) of the *MotionLoc* Screws with screw locking achieved using previously cleared Locking Caps (K042695, cleared 10/29/2004) that are threaded into the plate holes.

In the locked mode the *NCB* plate acts as an internal fixator without contact between the plate and the bone surface thus 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 (also previously cleared in K042695), which are threaded into the plate holes prior to plate insertion. Plates, screws, spacers and locking caps are made of titanium alloy.

Intended Use:

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

Comparison to Predicate Device:

The *MotionLoc* Screw for *NCB* Polyaxial Locking Plate System is similar in intended use, materials, sterility, and performance characteristics to the predicate devices. See the device description above for the design differences between the proposed and predicate devices.

Performance Data (Nonclinical and/or Clinical):

Non-Clinical Performance and Conclusions:

The results of non-clinical (lab and animal) performance testing demonstrate that the MotionLoc Screw for the NCB Polyaxial Locking Plate System presents no new issues regarding safety and effectiveness as compared to the predicate devices, and is substantially equivalent. Testing/analysis performed included: Construct fatigue testing (Distal Femur Plate with MotionLoc Screws, Proximal Tibia Plate with MotionLoc Screws); Starting load, driving torque and torque to failure testing (MotionLoc Screws); and Animal testing in an ovine tibial osteotomy model (locking compression plate with prototype MotionLoc Screws).

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. Stephen McKelvey
Senior Project Manager, Regulatory Affairs
P.O. Box 708
Warsaw, Indiana 46581

SEP 10 2010

Re: K101696
Trade/Device Name: MotionLoc™ Screw for NCB® Polyaxial Locking Plate System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HWC, HRS
Dated: June 15, 2010
Received: June 16, 2010

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. 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

K101696

510(k) Number (if known): K101696

SEP 10 2010

Device Name:

MotionLoc™ Screw for NCB® Polyaxial Locking Plate System

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 (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ____ (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 K101696