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

K123918
510(k) Summary

FEB 14 2013

Sponsor:
Zimmer, Inc.
P.O. Box 708
Warsaw, IN 46581-0708

Contact Person:
Stephen H. McKelvey
Senior Project Manager, Trauma Regulatory Affairs
Telephone: (574) 372-4944
Fax: (574) 371-8760

Date:
December 18, 2012

Trade Name:
Zimmer® *MotionLoc*™ Screw for *NCB*® Polyaxial Locking Plate System

Common Name:
Bone Screw

Classification Names and References:
Plate, Fixation, Bone
(21 CFR 888.3030, Product Code HRS)

Classification Panel:
Orthopedics/87

Predicate Devices:
The predicate devices are:

- Zimmer *MotionLoc* Screw For *NCB* Polyaxial Locking Plate System, K101696, cleared September 10, 2010
- Zimmer *NCB* Periprosthetic Femur Polyaxial Locking Plate System (K100111, cleared April 12, 2010)
- Zimmer *NCB* Straight Narrow Shaft Plates (K113718, cleared January 27, 2012)
- Synthes 4.5mm Locking Compression Plate (LCP) with Extended Indications (K082807, cleared January 13, 2009)

Purpose and Device Description:
This submission extends the indications of the existing *MotionLoc* Screw for *NCB* Polyaxial Locking Plate System by adding to the list of compatible plates to include the *NCB* Periprosthetic Proximal Femur, Distal Femur, Curved Femur Shaft and Straight Narrow Shaft plates and by allowing the *MotionLoc* screw to be used for fractures in osteopenic bone. In addition, this submission decreases the number of required *MotionLoc* screws in the shaft of the bone from four to three.

The *MotionLoc* Screw 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 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:

MotionLoc Screws, when used with the *NCB* Proximal Humeral or *NCB* Proximal Tibial plates, are indicated for temporary internal fixation and stabilization of fractures and osteotomies of long bones, including:

- Comminuted fractures
- Fractures in osteopenic bone
- Nonunions/Malunions

MotionLoc Screws, when used with the *NCB* Distal Femoral plates, are indicated for temporary internal fixation and stabilization of fractures and osteotomies of long bones, including:

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

MotionLoc Screws, when used with the *NCB* Straight Narrow Shaft plates, are indicated for temporary internal fixation and stabilization of humeral and tibial shaft fractures and osteotomies, including:

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

MotionLoc Screws, when used with the *NCB* Periprosthetic Proximal Femur, Distal Femur or Curved Femur Shaft plates, are 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 physical attributes (dimensions, materials, specifications manufacturing processes, etc.) have not changed from the predicate *MotionLoc* Screws. They still have 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. As before, these *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.

The proposed device is similar in intended use to the predicate devices.

Performance Data (Nonclinical and/or Clinical):

Non-Clinical Performance and Conclusions:

Sterilization Validation - Sterilization has not changed with the new indications or reducing the number of required *MotionLoc* screws in the shaft of the bone from four to three. These devices have been validated to demonstrate that at a minimum gamma dose of 20kGy these screws can be terminally sterilized to a SAL of 10^{-6} or better.

Shelf Life - Shelf life has not changed with the new indications or reducing the number of required *MotionLoc* screws in the shaft of the bone from four to three. Accelerated aging showed that these sterile screws have a shelf life of 10 years.

Sterile Packaging - Packaging has not changed. The sterile screws can withstand normal distribution and storage conditions and maintain the sterile barrier properties throughout the specified product shelf life.

Biocompatibility - Biocompatibility testing on the screw implant materials was conducted per ISO 10993-1 and Good Laboratory Practices (21 CFR § 58). All testing passed.

The new indications or reducing the number of required *MotionLoc* screws in the shaft of the bone from four to three does not change the fundamental scientific technology of any of the devices. Each sterile device uses the same operating principle and incorporates the same basic labeling.

Testing/Literature - The results of non-clinical (lab) performance testing demonstrate that the devices are safe and effective and substantially equivalent to the predicate devices when used with the newly indicated plate and for use with three screws. Testing/analysis performed included axial fatigue strength and torsional fatigue. In addition, data from the included literature references indicates that the devices are safe and effective for the newly indicated bone quality (osteopenic).

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 Center – WO66-G609
Silver Spring, MD 20993-0002

February 14, 2013

Zimmer, Incorporated
% Stephen H. McKelvey, MA, RAC
Senior Project Manager, Trauma Regulatory Affairs
P.O. Box 708
Warsaw, Indiana 46581-0708

Re: K123918
Trade/Device Name: Zimmer® MotionLoc™ Screw for NCB® Polyaxial Locking Plate System
Regulation Number: 21 CFR 888.3030
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HRS
Dated: December 18, 2012
Received: December 19, 2012

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,

Erin I. Keith

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

Enclosure

Indications for Use

510(k) Number (if known): K123918

Device Name:

Zimmer® *MotionLoc*™ Screw For *NCB*® Polyaxial Locking Plate System

Indications for Use:

MotionLoc Screws, when used with the *NCB* Proximal Humeral or *NCB* Proximal Tibial plates, are indicated for temporary internal fixation and stabilization of fractures and osteotomies of long bones, including:

- Comminuted fractures
- Fractures in osteopenic bone
- Nonunions/Malunions

MotionLoc Screws, when used with the *NCB* Distal Femoral plates, are indicated for temporary internal fixation and stabilization of fractures and osteotomies of long bones, including:

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

MotionLoc Screws, when used with the *NCB* Straight Narrow Shaft plates, are indicated for temporary internal fixation and stabilization of humeral and tibial shaft fractures and osteotomies, including:

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

MotionLoc Screws, when used with the *NCB* Periprosthetic Proximal Femur, Distal Femur or Curved Femur Shaft plates, are 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

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)

Michael C. Owens

Division of Orthopedic Devices