K120772 (pg. 1 of 4)

JUN 12 2012

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

510(k) Summary

Sponsor:	Zimmer, GmbH SulzerAllee 8 Winterthur, Switzerland CH-8404
Contact Person:	Romil Sheth Associate, Trauma Regulatory Affairs Telephone: (574) 371-1621 Fax: (574) 371-8760
Date:	March 12, 2012
Trade Name:	This is a bundled traditional 510(k). The trade names of the two devices bundled in this submission are: 1) *NCB* Periprosthetic Trochanter Plates and Screws 2) *NCB* Cable Button for *NCB* Polyaxial Locking Plate
Common Name:	1) Locking Plate System 2) Washer, Bolt, Nut
Classification Names and References	1) Plate, Fixation, Bone (21 CFR 888.3030) 2) Washer, Bolt, Nut (21 CFR 888.3030)
Predicate Devices:	1) *NCB* Periprosthetic Femur Polyaxial Locking Plate System, Manufactured by Zimmer, K100111, cleared April 12, 2010, and Pioneer Surgical Technology Extended GTR, Model 501-601, Manufactured by Pioneer Surgical Technology, K000734, cleared May 5, 2000. 2) *Cable Ready*® Cable Grip System Cable Button, Manufactured by Zimmer, K091799, cleared September 11, 2009

Device Description:

1) The *NCB* (Non-Contact-Bridging) Periprosthetic Trochanter Plates and Screws are a line of locking plates for the treatment of proximal femur fractures, which includes greater trochanter fractures and osteotomies. The *NCB* Periprosthetic Trochanter Plate and the Connection Screw for *NCB* Periprosthetic Trochanter Plate are used in combination with the *NCB* Periprosthetic Proximal Femur Plate, short (Length =115mm). The *NCB* Periprosthetic Trochanter Plate can also be used in combination with the existing *NCB* Periprosthetic Proximal Femur Plates (Length =245mm, 285mm, 324mm, 363mm, 401mm) from the *NCB* Periprosthetic Femur Polyaxial Locking Plate System. The *NCB* System technology used on the *NCB* Periprosthetic Proximal Femur Plates allows for polyaxial screw placement (30° cone) with screw locking achieved with the use of locking caps that are threaded into the plate holes. The *NCB* Periprosthetic Trochanter Plate contains threaded conical holes which allow for monoaxial screw placement using locking screws with threaded heads. Non-locking cortical screws can also be used. All the plates are made of Ti-6Al-4V alloy. The Connection Screw for *NCB* Periprosthetic Trochanter Plate is also made of Ti-6Al-4V alloy.

2) The *NCB* Cable Button for *NCB* Polyaxial Locking Plate is a temporary internal fixation component used in conjunction with Zimmer *NCB* Plates, Zimmer *NCB* Periprosthetic Plates and Cerclage Cables. The Cable Button is threaded into a vacant screw hole of Zimmer *NCB* Plates or Zimmer *NCB* Periprosthetic Plates and provides a positioning point for a Cerclage Cable. The Cable Button is made up of Ti-6Al-4V alloy and is color anodized.

Intended Use:

1) The *NCB* Periprosthetic Trochanter Plate when used in combination with the *NCB* Periprosthetic Proximal Femur Plate, short (Length =115mm) is indicated for temporary internal fixation and stabilization of fractures and osteotomies of the greater trochanter.

The *NCB* Periprosthetic Trochanter Plate when used in combination with the *NCB* Periprosthetic Proximal Femur Plates (Length =245mm, 285mm, 324mm,

363mm, 401mm) is indicated for temporary internal fixation and stabilization of fractures and osteotomies of the proximal femur.

In addition, both combinations are indicated for:

- Re-attachment of the greater trochanter following osteotomy in THA
- Re-attachment of the greater trochanter following fracture of greater trochanter
- Periprosthetic fractures
- Comminuted fractures
- Fractures in osteopenic bone
- Nonunions
- Malunions

2) The Cable Button is intended for use in combination with the Zimmer Locking Bone Plating Systems and Cerclage Cables, to stabilize multiple fractures or butterfly fragments in long bones.

Comparison to Predicate Device: The *NCB* Periprosthetic Trochanter Plates and Screws as well as the *NCB* Cable Button for *NCB* Polyaxial Locking Plate are similar in intended use, materials, sterility, and performance characteristics to the predicate device(s).

Performance Data (Nonclinical And/or Clinical):

Non-Clinical Performance and Conclusions:

1) Testing/Analysis performed included; Torsional strength evaluation of the Connection Screw for *NCB* Periprosthetic Trochanter Plate, Fatigue strength evaluation of the *NCB* Periprosthetic Trochanter Plate with and without using cable and hex button, Fatigue strength evaluation of the *Cable Ready* Cable Grip System for Greater Trochanteric Reattachment (predicate device), Stiffness evaluation of the *NCB* Periprosthetic Trochanter Plate and Evaluation of Removal Torque of the ULS *Tivanium*® Ti-6Al-4V Alloy 3.5mm locking screws.

2) Testing/Analysis performed included; Evaluation of seating and removal torque of a *NCB* Cable Button and Loading analysis of a *NCB* Cable Button.

The results of non-clinical (lab) performance testing demonstrate that the devices are safe and effective and substantially equivalent to the predicate devices.

Also, a literature review was conducted to substantiate the use of the *NCB* Periprosthetic Trochanter Plates and Screws 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, GmbH
% Mr. Romil Sheth
Associate, Trauma Regulatory Affairs
P.O. Box 708
Warsaw, Indiana 46581-0708

JUN 12 2012

Re: K120772
Trade/Device Name: *NCB* Periprosthetic Trochanter Plates and Screws and *NCB* Cable Button for *NCB* Polyaxial Locking Plate
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS, HTN, HWC
Dated: March 12, 2012
Received: March 14, 2012

Dear Mr. Sheth:

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 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,

for 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): K120772

Device Name:
NCB Periprosthetic Trochanter Plates and Screws

Indications for Use:

The *NCB* Periprosthetic Trochanter Plate when used in combination with the *NCB* Periprosthetic Proximal Femur Plate, short (Length =115mm) is indicated for temporary internal fixation and stabilization of fractures and osteotomies of the greater trochanter.

The *NCB* Periprosthetic Trochanter Plate when used in combination with the *NCB* Periprosthetic Proximal Femur Plates (Length =245mm, 285mm, 324mm, 363mm, 401mm) is indicated for temporary internal fixation and stabilization of fractures and osteotomies of the proximal femur.

In addition, both combinations are indicated for:

- Re-attachment of the greater trochanter following osteotomy in THA
- Re-attachment of the greater trochanter following fracture of greater trochanter
- Periprosthetic fractures
- Comminuted 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)

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

510(k) Number K120772

Indications for Use

510(k) Number (if known): K120772

Device Name:
NCB Cable Button for *NCB* Polyaxial Locking Plate

Indications for Use:

The Cable Button is intended for use in combination with the Zimmer Locking Bone Plating Systems and Cerclage Cables, to stabilize multiple fractures or butterfly fragments in 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)

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

510(k) Number K120772