SEP 11 2009

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

Summary of Safety and Effectiveness

Sponsor:	Zimmer, Inc. P.O. Box 708 Warsaw, IN 46581-0708
Contact Person:	Anthony Francalancia, RAC Senior Associate, Regulatory Affairs Telephone: (574) 372-4570 Fax: (574) 372-4605
Date:	September 9, 2009
Trade Name:	*Cable Ready*® Cable Grip System Cable Button
Common Name:	Washer, Bolt, Nut, Orthopedic
Classification Name and Reference:	HTN - Washer, Bolt, Nut, Orthopedic 21 CFR § 888.3030
Predicate Device:	Hex Button, manufactured by Pioneer Laboratories, K992617, cleared October 27, 1999. Cerclage Positioning Pin, manufactured by Synthes, K992891, cleared November 2, 1999.
Device Description:	The *Cable-Ready* Cable Grip System Cable Button is a temporary internal fixation component used in conjunction with Zimmer Locking Bone Plates and Cerclage Cables. The Cable Button is threaded into a vacant screw hole of Zimmer Locking Bone Plates and provides a positioning point for a Cerclage Cable. The Cable Button is available in Titanium (Ti-6AL-4V Alloy) and Stainless Steel (22-13-5 SST).
Intended 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.
Comparison to Predicate Device:	The proposed devices, like the predicates, are used in conjunction with bone plates and cerclage devices to provide a positioning point for the

cerclage device. The proposed devices are made of similar materials (Stainless Steel and Titanium Alloy) as the predicates.

Performance Data (Nonclinical and/or Clinical):

Non-Clinical Performance and Conclusions:

Testing and Engineering Analysis demonstrates that the proposed devices meet performance requirements.

Clinical Performance and Conclusions:

Clinical data and conclusions were not needed for these devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

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Zimmer, Inc.
% Anthony Francalancia, RAC
Senior Associate, Regulatory Affairs
P.O. Box 708
Warsaw, Indiana 46581-0708

Re: K091799
Trade/Device Name: *Cable Ready*® Cable Grip System Cable Button
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HTN
Dated: August 19, 2009
Received: August 20, 2009

Dear Mr. Francalancia:

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,

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): K091799

Device Name:

Cable-Ready® Cable Grip System Cable Button

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)

for MXM

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

510(k) Number K091799