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Summary of Safety and Effectiveness

Submitter:	Zimmer, Inc. P.O. Box 708 Warsaw, IN 46581-0708
Contact Person:	Stephen H. McKelvey Manager, Regulatory Affairs Telephone: (574) 372-4944 Fax: (574) 372-4605
Date:	November 19, 2003
Trade Name:	*Minimally Invasive Solutions*™ Osteotomy Guide Instrument
Common Name:	Osteotomy Guide
Classification Name and Reference:	Electrosurgical Cutting and Coagulation Device and Accessories, 21 CFR § 878.4400
Predicate Device:	Saphyre Bipolar Ablation Probes, manufactured by Smith and Nephew, Inc., K031371, cleared May 23, 2003.
Device Description:	The Osteotomy Guide will be used as an aid to help the surgeon mark the periosteal location of the osteotomy cut in the calcar of the femur as part of a replacement surgery.
Intended Use:	This device is intended for local coagulation of soft tissues during minimally invasive orthopedic surgeries, such as, but not limited to hip, knee, shoulder and elbow arthroplasty by use of high-frequency electrical current. This local coagulation serves to mark the tissue to aid the surgeon in the location of subsequent osteotomies.
Comparison to Predicate Device:	Both the predicate and proposed device are used to coagulate soft tissue.

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Performance Data (Nonclinical and/or Clinical):

Non-Clinical Performance and Conclusions:

UL Testing was performed per IEC 60601-1 (1988) second edition with Amendment No. 1 (1991) and No. 2 (1995) and passed all applicable tests.

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
9200 Corporate Boulevard
Rockville MD 20850

FEB - 4 2004

Mr. Stephen H. McKelvey
Manager, Regulatory Affairs
Zimmer, Inc.
P.O. Box 708
Warsaw, Indiana 46581-0708

Re: K033652
Trade/Device Name: Minimally Invasive Solutions™ Osteotomy Guide Instrument
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: November 19, 2003
Received: November 20, 2003

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 (301) 594-4659. 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 Miriam C. Provost

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): K033652

Device Name:

Minimally Invasive Solutions™ Osteotomy Guide Instrument

Indications for Use:

This device is intended for local coagulation of soft tissues during minimally invasive orthopedic surgeries, such as, but not limited to hip, knee, shoulder and elbow arthroplasty by use of high-frequency electrical current. This local coagulation serves to mark the tissue to aid the surgeon in the location of subsequent osteotomies.

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)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

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