K033011

FEB 12 2004

Summary of Safety and Effectiveness

Submitter:	Zimmer, Inc. P.O. Box 708 Warsaw, IN 46581-0708
Contact Person:	Stephen McKelvey Manager, Regulatory Affairs Telephone: (574) 372-4944 Fax: (574) 372-4605
Date:	September 25, 2003
Trade Name:	Zimmer Ortho Guidance Systems – Knee Instruments
Common Name:	Image Guided Instrument
Classification Name and Reference:	Stereotaxic Instrument 21 CFR § 882.4560
Predicate Device:	Catheter Introducer for the StealthStation System, manufactured by Medtronic Surgical Navigation Technologies, K022126, cleared January 3, 2003.
Device Description:	This submission is for Zimmer orthopedic manual knee instruments modified to accept an Medtronic Image Guidance System (IGS) array and to be used with the Medtronic StealthStation® System
Intended Use:	Zimmer Knee Ortho Guidance Instruments are intended as accessories to Image Guided Surgery systems and are indicated for any knee orthopedic medical condition in which the use of stereotaxic surgery may be appropriate, and where reference to a rigid anatomical structure, such as a long bone, can be identified relative to a CT or MR based model or fluoroscopy images of the anatomy. Example orthopedic procedures for these instruments include, but are not limited to:

- Total Knee Arthroplasty (Primary and Revision)
- Unicompartmental Knee Arthroplasty (Primary and Revision)
- Minimally Invasive Knee Orthopedic Procedures

Comparison to Predicate Device:

Both the predicate and proposed devices are indicated for use with Image Guidance Surgery systems. Both are accessory instruments.

Performance Data (Nonclinical and/or Clinical):

Non-Clinical Performance and Conclusions:

No testing was needed for these devices. QSR validation and verification will be conducted for instruments used in conjunction with Medtronic StealthStation Image Guidance Systems.

Clinical Performance and Conclusions:

Clinical data and conclusions were not needed for these devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 12 2004

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

Re: K033011
Trade/Device Name: Zimmer Ortho Guidance Systems – Knee Instruments
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: II
Product Code: HAW
Dated: December 10, 2003
Received: December 11, 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): K033011

Device Name:

Zimmer Ortho Guidance Systems – Knee Instruments

Indications for Use:

Zimmer Knee Ortho Guidance Instruments are intended as accessories to Image Guided Surgery systems and are indicated for any knee orthopedic medical condition in which the use of stereotaxic surgery may be appropriate, and where reference to a rigid anatomical structure, such as a long bone, can be identified relative to a CT or MR based model or fluoroscopy images of the anatomy. Example orthopedic procedures for these instruments include, but are not limited to:

Total Knee Arthroplasty (Primary and Revision)
Unicompartmental Knee Arthroplasty (Primary and Revision)
Minimally Invasive Knee Orthopedic Procedures

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

510(k) Number K033011