K060556

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Summary of Safety and Effectiveness

JUL 31 2006

Submitter:	Zimmer, Inc. P.O. Box 708 Warsaw, IN 46581-0708
Contact Person:	Stephen H. McKelvey Manager, Corporate Regulatory Affairs Telephone: (574) 372-4944 Fax: (574) 372-4605
Date:	July 26, 2006
Trade Name:	BRIGIT Surgical Device
Common Name:	Computer assisted surgical device
Classification Name and Reference:	Stereotaxic instrument, 21 CFR § 882.4560
Predicate Device:	Neuromate Stereotactic system, manufactured by Integrated Surgical Systems, Inc., K963256, cleared May 9, 1997. Navitrack System – S&N Image Free Knee, manufactured by Orthosoft, K043536, cleared January 14, 2005. Medtronic Stealth Station, manufactured by Medtronic, K050438, cleared June 2, 2005. Zimmer Ortho Guidance Systems – Knee Instruments, manufactured by Zimmer, Inc., K033011, cleared February 12, 2004. Zimmer Ortho Guidance Systems – Hip Instruments, manufactured by Zimmer, Inc., K033223, cleared February 18, 2004. Zimmer Computer Assisted Solutions – Electromagnetic and Imageless Knee Instrumentation, manufactured by Zimmer, Inc., K052425, cleared December 28, 2005.

Device Description:

BRIGIT Surgical Device is a computer controlled electromechanical multi-jointed arm. It is intended to be used in the operating room for the spatial positioning and orientation of an instrument holder or tool guide to be used by the surgeon to manually guide orthopedic instruments.

BRIGIT Surgical Device assists the surgeon in:

- determining reference alignment axes in relation to anatomical landmarks,
- planning the position of instruments relative to these axes,
- and providing a stable, accurate and reproducible mechanical guidance of surgical instruments in accordance with said planning, while not directly entering in contact with the patient.

BRIGIT Surgical Device can be shifted into a "cooperative mode" where the surgeon can manually move the arm anywhere in the operating field by simply grabbing the tip. Pinpoint collection of anatomical landmarks is carried out with BRIGIT Surgical Device and its pointing instrument in cooperative mode.

Adequate position of the guide is derived from three-dimensional calculations performed from desired surgical planning parameters and spatial positions of anatomical landmarks.

BRIGIT Surgical Device offers the rigidity essential for accurate and steady support of the guide.

Intended Use:

BRIGIT Surgical Device is a computer controlled electromechanical multi-jointed arm. It is intended to be used in the operating room for the spatial positioning and orientation of an instrument holder or tool guide to be used by the surgeon to manually guide orthopedic instruments.

It is indicated for any 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 digitized landmarks of the anatomy.

Example orthopedic procedures for these instruments include, but are not limited to:

- Total Knee Arthroplasty (Primary and Revision)
- Unicompartmental Knee Arthoplasty (Primary and Revision)
- Minimally Invasive Knee Orthopedic Procedures
- Total or Hemi-Hip Arthroplasty (Primary and Revision)
- Minimally Invasive Hip Orthopedic Procedures
- Tumor Resection and Bone/Joint Reconstruction
- Stabilization or Repair of Pelvic/Femoral Fractures

Comparison to Predicate Device:

The technological characteristics, features, specifications, materials, mode of operation, and intended use of the BRIGIT Surgical Device are substantially equivalent to the predicate devices listed above.

The differences that exist between the devices do not raise new issues of safety or effectiveness regarding the BRIGIT Surgical Device.

Performance Data

Testing was carried out to assure compliance with recognized electrical safety standards: IEC 60601-1 standard for electrical safety and IEC 60601-2 standard for electromagnetic compatibility.

Tests were also carried out to satisfy the requirements of the FDA Guidance for the Content of Premarket Submisions for Software Contained in Medical Devices.

Device accuracy tests were performed to validate the accuracy and repeatability of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

JUL 3 1 2006

Re: K060556
Trade/Device Name: BRIGIT Surgical Device
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: II
Product Code: HAW
Dated: July 6, 2006
Received: July 7, 2006

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 (240) 276-0115. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Mark N. Melkerson
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): K060556

Device Name:

BRIGIT Surgical Device

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- Stabilization or Repair of Pelvic/Femoral Fractures

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)

Herbert Lerner MD

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

510(k) Number K060556