SEP 1 5 2003

K03/337

Summary of Safety and Effectiveness

Applicant/Sponsor:	Biomet Orthopedics, Inc. P.O. Box 587 Warsaw, Indiana 46581-0587
Contact Person:	Kristine C. (Kacy) Arnold, RN. MBA Telephone: (574) 267-6639 Fax: (574) 372-1683
Proprietary Name:	Acumen™ Surgical Navigation System
Common Name:	Instrument, Stereotaxic
Classification Name:	Stereotaxic Instrument (21 CFR 882.4560)
Device Classification:	Class II
Legally Marketed Devices to Which Substantial Equivalence is claimed:	Voyager™ Linux (K023975) FluroLab® Plus (K013025)

Device Description: The Acumen™ Surgical Navigation System includes general instrumentation that is utilized with application specific software developed and supplied by Z-KAT, Inc. (Hollywood, Florida).

Passive markers (spheres) are attached onto the Acumen™ instrumentation. An infrared light source generated by the camera reflects off of the passive markers to allow their position and orientation to be identified. The Acumen™ instruments are used as: 1) an independent instrument, 2) connected to instruments, which are attached to the patient, or 3) connected to the associated implant preparation and insertion instrumentation.

All Acumen™ instruments will have a minimum of three (3) passive markers to be tracked by the camera system. They will also be rigidly connected to the instrumentation. Each Acumen™ instrument, utilized in the surgical procedure, will have a defined geometry of the passive marker position for a unique identification by the camera and software system.

The instruments can be utilized with knee and trauma applications. The Acumen™ instruments are designed as one-time use components.

Intended Use: The Acumen™ Surgical Navigation System is intended to assist the surgeon in providing orientation and reference information to anatomical structures during open or percutaneous orthopedic procedures. The Acumen™ Navigation System is indicated for use in surgical knee and trauma procedures, in which the use of stereotaxic surgery may be appropriate, and where reference to rigid anatomical bony structures can be identified relative to a CT or MRI based model, fluoroscopy or an imageless model of the anatomy.

These procedures include, but are not limited to knee arthroplasty or trauma reconstructive procedures.

Summary of Technologies: The Acumen™ Surgical Navigation System's technological characteristics are similar to or identical to the predicate devices.

Non-Clinical Testing: Software verification and validation was performed to establish substantial equivalence to the predicate devices.

Clinical Testing: Clinical testing was not used to establish substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 5 2003

Ms. Kristine C. Arnold, RN, MBA
Regulator Affairs Specialist
Biomet, Inc.
56 E. Bell Drive
P.O. Box 587
Warsaw, Indiana 46581-0587

Re: K031337
Trade/Device Name: Acumen™ Navigation System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: II
Product Code: HAW
Dated: July 10, 2003
Received: July 14, 2003

Dear Ms. Arnold:

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,

Miriam C. Provost

for 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

510 (k) Number (if known) : K031337

Device Name: **Acumen™ Surgical Navigation Systems**

Indications for Use:

The Acumen™ Surgical Navigation System is intended to assist the surgeon in providing orientation and reference information to anatomical structures during open or percutaneous orthopedic procedures. The Acumen™ System is indicated for use in surgical knee and trauma procedures, in which the use of stereotaxic surgery may be appropriate, and where reference to rigid anatomical bony structures can be identified relative to a CT or MRI based model, fluoroscopy or an imageless model of the anatomy. These procedures include, but are not limited to knee arthroplasty or trauma reconstructive procedures.

Miriam C. Provost

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

510(k) Number K031337

(PLEASE DO NOT WRITE BELOW THIS LINE. CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter-Use_____
(Per 21 CFR 801.109) (Optional Format 1-2-96)