BIOMET INC

510(k) Summary
InnerVue™ Diagnostic Scope System

JAN 14 2008

Preparation Date: December 20, 2007

Applicant/Sponsor:
Biomet Sports Medicine
56 East Bell Drive
Warsaw, Indiana 46582

Contact Person:
Susan Alexander
Regulatory Affairs Specialist

Proprietary Name: InnerVue™ Diagnostic Scope System

Common Name: Arthroscope, endoscope

Classification Name:
Arthroscope, 21 CFR §888.1100, HRX
Endoscope, 21 CFR §876.1500, GCJ

Legally Marketed Devices To Which Substantial Equivalence Is Claimed:

Video Arthroscope	K043395	Smith & Nephew
InnerVue™ Diagnostic Scope System	K040604	Arthrotek, Inc. (Biomet Sports Medicine)
Arthrex Arthroscopes	K030096	Arthrex, Inc.
METRx™ System	K002931	Medtronic Sofamor Danek
Integrated Endoscopy System	K920800	Integrated Endoscopy System

Device Description: The InnerVue™ Diagnostic Scope System consists of five (5) main parts: hardware, software, instrumentation and procedural kit(s).

Hardware: The hardware consists of the following components: Monitor, keyboard, image processor, Xenon light source, camera unit, power supply, printer, handpiece (which incorporates the camera head and light cable), a slide-out working surface and a storage drawer.

Software: The software enhances the image from the scope to remove fiber optic pixilation without adding distortion. The software allows the operator to record and print still images as well as record and archive audio and video information recorded during the procedure.

Scope: A rigid fiber optic scope designed for one-time use.

Supplementary Instruments: Supplementary instruments consist of four (4) pieces that can be used interchangeably throughout the procedure. The four components are a cannula, a trocar, an obturator, and a cannula plug. Both disposable and reusable supplementary instruments are available with the system.

Procedural Kits: Supplementary items to assist in the surgical procedure.

Clinical Testing: None provided as a basis for substantial equivalence.

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Toll Free: 800.348.9500
Office: 574.267.6639
Main Fax: 574.267.8137
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Shipping Address:
56 East Bell Drive
Warsaw, IN 46582

Indications for Use: The InnerVue™ Diagnostic Scope System is indicated for use in diagnostic and operative arthroscopic and endoscopic procedures to provide illumination and visualization of an interior cavity of the body through either a natural or surgical opening. Examples of generic surgical use include the visualization of joints within the body. These joints can include, joints located in the torso/trunk, upper/lower extremities, and the temporomandibular joint.

Summary of Technologies: The technological characteristics of the InnerVue™ Diagnostic Scope System are the same as, or similar to, the predicate devices.

Performance and Safety Testing

The InnerVue™ Diagnostic Scope System complies with Can/CSA C22.2 No 601.1-M90 - Safety of Medical Electrical Equipment, part 1., General; CSA 601.1 Supplement 1:1994 - Requirements for Safety, CSA 601.1 Amendment 2:1998, CAN/CSA C22.2 No. 60601-2-18-01 - Particular Requirements for the Safety of Endoscopic Equipment, UL Std No 60601-1(1st Edition) - Safety of Medical Equipment , Part I: General Requirements for Safety and IEC 60601-2-18(1996) 2nd Edition.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 14 2008

Biomet Manufacturing Corp.
% Ms. Susan Alexander
Regulatory Affairs Specialist
P.O. Box 587
Warsaw, Indiana 46581-0587

Re: K072879
Trade/Device Name: InnerVue™ Diagnostic Scope System
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: II
Product Code: HRX
Dated: December 20, 2007
Received: December 21, 2007

Dear Ms. Alexander:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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,

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):_____

Device Name: InnerVue™ Diagnostic Scope System

Indications for Use:

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Prescription Use ___YES___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use __NO__ (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)

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

510(k) Number K072879