K040604

JUN - 4 2004

BIOMET

510(k) Summary

Applicant/Sponsor: Arthrotek, Inc.
(A wholly owned subsidiary of Biomet, Inc.)
56 East Bell Drive
P.O. Box 587
Warsaw, Indiana 46581-0587

Contact Person: Kacy Arnold, RN, MBA
Regulatory Specialist

Proprietary Name: InnerVue™ Diagnostic Scope System

Common Name: Diagnostic Endoscope

Classification Name: Endoscope

Legally Marketed Devices To Which Substantial Equivalence Is Claimed:

- Davlite Microendoscope, K020310

Device Description:
The InnerVue™ Diagnostic Scope System consists of 5 main parts; the hardware, the software, the scope, the instrumentation and the procedural kit.

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 pixelation. 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 fiberoptic scope designed for one time use.

Supplemental Instruments:
Supplemental instruments consist of 4 pieces that can be used interchangeably throughout the procedure. The four components of the instrumentation are the cannula, the trocar, the obturator, and the cannula plug.

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Warsaw, IN 46581-0587

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56 E. Bell Drive
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574.267.6639

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574.267.8137

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biomet@biomet.com

Procedural Kit:
The procedural kit contains many sterile items to aid in the procedure.

Indications for Use: This device is to be used by a trained physician for viewing the interior cavity of the human body through either a surgical or natural opening.

Intended Use: Single use (disposable) scope.

Summary of Technologies: The InnerVue™ Diagnostic Scope System technological characteristics are similar to predicate devices.

Non-Clinical Testing: Establishment of equivalence is based on similarities of intended use, design and, materials, physical characteristics and geometry between the InnerVue™ Diagnostic Scope System and Davlite Microendoscope (K020310)

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 4 2004

Ms. Kacy Arnold, RN, MBA
Arthrotek, Inc.
56 E. Bell Drive
P.O. Box 587
Warsaw, Indiana 46581

Re: K040604
Trade/Device Name: InnerVue™ Diagnostic Scope System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ
Dated: March 5, 2004
Received: March 8, 2004

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,

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): K040604

Device Name: **InnerVue™ Diagnostic Scope System**

Indications For Use:

This device is to be used by a trained physician for viewing the interior cavity of the human body through either a surgical or natural opening.

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)

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

510(k) Number K040604