K020761

APR 0 3 2002

BIOMET

CORPORATE HEADQUARTERS

Summary of Safety and Effectiveness

Applicant or Sponsor: Arthrotek. Inc.
(A wholly owned subsidiary of Biomet, Inc.)
56 East Bell Drive
P.O. Box 587
Warsaw, Indiana 46581-0578

Contact Person: Patricia Sandborn Beres
Biomet Orthopedics Inc.
Phone: (574) 267-6639
FAX: (574) 372-1683

Proprietary Name: Power Tek II

Common Name: Arthroscopic shaver console and handpiece

Classification Name: Surgical instrument motors and accessories/attachments (21 CFR 878.4820)

Legally Marketed Devices to which Substantial Equivalence is Claimed: The Integrated Endoscopy System 1000 (K920800)

Device Description: The Arthrotek Power Tek II arthroscopic shaver system is intended to provide a shaver unit that will meet the surgeon's needs and patient's needs for abrasion arthroplasty, synovectomy or intra-articular cutting and shaving. The system consists of four pieces. The Control Console houses the microprocessor, shaver driver, mode and speed controls, and operator display. A Remote Control allows the user to access all controls from the surgical field. The Footswitch allows the surgeon easy on/off and forward/reverse/oscillate selection and control. The Shaver Handpiece is capable of running from 400 to 12,000 rpm's, with linear suction control for debris aspiration.

Intended Use: The Power Tek II shaver system is a powered instrument for orthopedic applications including abrasion arthroplasty, synovectomy or intra-articular cutting and shaving. The device is intended for use in the knee, shoulder, wrist, temporal-mandibular joint, ankle, and elbow.

Summary of Technologies: The materials, process and design of the Power Tek II are similar to the predicate device.

Non-Clinical Testing: Validation testing included IEC 601-1 Safety Testing, UL certification, and Electromagnetic Compatibility as well as software validation, functional validation and cleaning and sterilization validation.

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

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Patricia Sandborn Beres
Senior Regulatory Specialist
Biomet, Inc.
P.O. Box 587
Warsaw, Indiana 46581-0587

APR 0 3 2002

Re: K020761
Trade/Device Name: Power Tek II
Regulation Number: 888.1100
Regulation Name: Arthroscope
Regulatory Class: II
Product Code: HRX
Dated: March 6, 2002
Received: March 7, 2002

Dear Ms. Beres:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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): K020761

Device Name: Power Tek II

Indications For Use:

The Power Tek II shaver system is a powered instrument for orthopedic applications including abrasion arthroplasty, synovectomy or intra-articular cutting and shaving. The device is intended for use in the knee, shoulder, wrist, temporal-mandibular joint, ankle, and elbow.

Miriam C. Provost

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

510(k) Number K020761

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)