K 093409

510(k) Summary

Submitter: Medical Vision
Nacka, Sweden

FEB 2 4 2010

Contact Information: C. G. Bundy Associates, Inc.
435 Rice Creek Terrace
Fridley, MN 55432

Submission Date: October 29, 2009

Device Name and Classification: Power Pump® Arthroscopy System, Class II
Product Code: HRX

Equivalent Device Identification:

Device: Future Medical Systems FMS DUO, K954465
SmartVision® Feature: Gambro Dialysis Machine, K771227 and Baxter Altratouch system 1000 dialysis machine, K954987

Device Description:

The PowerPump provides liquid irrigation and aspiration for arthroscopic procedures in one unit through two individual roller pumps. Both roller pumps are software controlled and automatically manage fluid and joint pressure based on procedure settings chosen by the user. If needed, both flow and pressure settings can be individually adjusted. By controlling both inflow and outflow, the PowerPump accurately regulates pressure and flow in the joint. The PowerPump also provides suction when used in conjunction with a shaver.
The PowerPump consists of the following articles:

1. PowerPump Unit
2. Non-sterile Foot Control
3. Non-sterile Power Cord
4. Disposable, sterile Patient Cassette
5. Disposable, sterile Day Cassette
6. Disposable, sterile PowerPump Irrigation Tubing

Intended Use:
The PowerPump is a dual arthroscopic pump system intended to provide fluid distension and irrigation of the knee, shoulder, hip, elbow, ankle and wrist joint cavities and fluid suction during diagnostic and operative arthroscopic procedures.

Summary of Testing: The PowerPump has been tested for function, performance and safety. Test results show that all specifications have been met.

Conclusion:
The PowerPump arthroscopy pump and the predicate device FMS DUO are substantially equivalent. Both pumps are intended to be used for providing distention pressure of body joints by pressurizing irrigation liquid, and to aspirate the liquid from the joint. Differences that exist between the devices are minor and do not affect the safety and effectiveness of the PowerPump.

The optical detection (SmartVision) feature is equivalent to blood and debris detection features used with dialysis machines. The addition of this well-known technology to the PowerPump does not affect the safe and effective intended use of the device as an Arthroscopy pump.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Medical Vision AB
% C. G. Bundy Associates, Inc.
Constance G. Bundy
435 Rice Creek Terrace
Fridley, Minnesota 55432

FEB 2 4 2010

Re: K093409
Trade/Device Name: PowerPump® Arthroscopy System
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: Class II
Product Code: HRX
Dated: February 17, 2010
Received: February 22, 2010

Dear Constance G. Bundy:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K093409

Device Name: PowerPump® Arthroscopy System

Indications For Use:

The PowerPump is a dual arthroscopic pump system intended to provide fluid distension and irrigation of the knee, shoulder, hip, elbow, ankle and wrist joint cavities and fluid suction during diagnostic and operative arthroscopic procedures.

Prescription Use __X_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 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 Surgical, Orthopedic,
and Restorative Devices

510(k) Number K093409