KARL STORZ
Endoscopy-America, Inc.

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OCT 18 2010

K093471

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Devices Act (SMDA) of 1990 and 21 CFR 807.92. All data included in this document are accurate and complete to the best of KSEA's knowledge.

Submitter: Karl Storz Endoscopy-America, Inc.
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Contact Person: Crystal Dizol
Regulatory Affairs Specialist
Email: cdizol@ksea.com

Date Prepared: September 16, 2010

Device Trade Name: Karl Storz ARTHROPUMP POWER Irrigation/Suction Pump

Common Name: Arthroscopic pump

Classification Name: Arthroscope and accessories

Regulation Number: 21 CFR 884.1730

Product Code: HRX

Predicate Device(s):
Future Medical Systems, Inc.: FMS Duo (K954465)
Karl Storz: Arthropump Plus (K971649)

Device Description:
The Karl Storz ARTHROPUMP POWER is a combined irrigation and suction pump for dilation and irrigation of joint capsules with a fluid. Both roller pumps are software controlled and automatically manage fluid and joint pressure based on settings chosen by the user. If desired, both flow and pressure settings can be individually adjusted. The device is used as part of a system that includes the unit, a footswitch and tubing, and can support integrated use of a shaver.

Intended Use:
The Karl Storz ARTHROPUMP POWER Irrigation/Suction Pump is intended for use by qualified surgeons to provide irrigation/aspiration to the surgical site during arthroscopic surgical procedures in the joints of the shoulder, knees, ankle, elbow, wrist, and hip.

Technological Characteristics:
The KARL STORZ ARTHROPUMP POWER Irrigation/Suction Pump utilizes microprocessor controlled dual peristaltic pump technology to maintain user-set pressure and flow, and to also perform lavage and hemostasis as necessary.

Non-Clinical Performance Data:
The KARL STORZ ARTHROPUMP POWER has been tested for function, performance and safety. Test results show that all specifications have been met.

Determination of Substantial Equivalence:
The Karl Storz ARTHROPUMP POWER Irrigation/Suction Pump is substantially equivalent to the predicate devices since the basic features, design, and intended use are similar. The minor differences between the Karl Storz ARTHROPUMP POWER Irrigation/Suction Pump and the predicate devices raise no new issues of safety and effectiveness, as these design differences have no effect on the function or intended use of the devices. Where differences in performance or technology exist, it has been demonstrated that they do not adversely impact safety or effectiveness.

Conclusions:
The Karl Storz ARTHROPUMP POWER is substantially equivalent to the identified predicate devices and does not raise any new issues of safety and efficacy.

Att: Substantial Equivalence Table for Karl Storz ARTHROPUMP POWER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OCT 18 2010

Karl Storz Endoscopy-America, Inc.
% Ms. Crystal Dizol
Regulatory Affairs Specialist
2151 East Grand Avenue
El Segundo, California 90245-5017

Re: K093471
Trade/Device Name: Karl Storz ARTHROPUMP POWER Irrigation/Suction Pump
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: Class II
Product Code: HRX
Dated: September 16, 2010
Received: September 20, 2010

Dear Ms. Dizol:

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,

For Peter Dr DEP DIR

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

OCT 18 2010

510(k) Number (if known): K093471

Device Name: Karl Storz ARTHROPUMP POWER Irrigation/Suction Pump

Indications for Use: The Karl Storz ARTHROPUMP POWER Irrigation/Suction Pump is intended for use by qualified surgeons to provide irrigation/aspiration to the surgical site during arthroscopic surgical procedures in the joints of the shoulder, knees, ankle, elbow, wrist, and hip.

Prescription Use: X AND/OR Over-The-Counter Use: _____
(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 K093471