MAY 19 2010 K093479

Modern Medical Equipment Manufacturing Ltd
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Tel:(852)2420 9068, Fax:(852)2481 1234 , Web address: www.modernmedical.com.hk

510(k) Summary

Owner's name: Modern Medical Equipment Manufacturing Ltd
Address: 5F,Gold King Ind.Bldg.,35 Tai Lin Pai Rd.. Kwai Chung, Hong Kong, China
Phone number : +852 24209068 , Fax number : +852 24811234
Name of contact person: Eugene Yeung
Date the summary was prepared: 19 October 2009
Name of the device: Disposable Suction And Irrigation System
Trade or proprietary name: Disposable Suction And Irrigation System
Common or usual name: Suction And Irrigation System
Classification name: Laparoscope, General & Plastic Surgery
Substantially equivalent device: Applied SI Suction Irrigator

Description of Device:

The Disposable Suction And Irrigation System is composed of a stainless steel Suction / Irrigation Probe which is connected to a handle having two trumpet type valves. Using the fingers, the action of depressing one valve will control the flow of the irrigation fluid from the Poly Venyl Chloride (PVC) tubing through the irrigation probe and be delivered onto the site of surgery. By depressing the other valve would enable the action of suction to remove blood and tissue debris from the site of surgery through the suction probe and these will be transported through the PVC tubing and be deposited into a waste container.

The handle is joined to two PVC tubes. One divides itself into two branches to conduct irrigation fluids from a saline bag. The clamp is used to hold the two tubes in a vertical position. This irrigation fluid passes down the tubes, then through the Suction / Irrigation Probe and is deposited onto the surgical site. The other tube will conduct waste tissue debris or blood or smoke. A vacuum pump will be connected to the Suction Connection end to draw the tissue debris or blood or smoke from the site of surgery, through the stainless steel Suction / Irrigation Probe and these are transported through this PVC tubing until they are deposited into a waste container. This device is for single use only.

Intended Use of Device:

The Disposable Suction And Irrigation System is used to deliver sterile irrigation fluids to surgical sites during laparoscopic procedures and to remove fluid waste, tissue debris and smoke from the surgical site.

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The technological characteristics of The Disposable Suction And Irrigation System as compared to the predicate device - Applied SI Suction Irrigator,. are found to be very similar. This device has the same technological characteristics in terms of design, structure, material composition, indication for use, intended use are similar as the predicate device. A summary of the technological characteristics of the new device in comparison to those of the predicate device was included in the main submission file.

Conclusion:

It is demonstrated that the device Disposable Suction And Irrigation System is as safe, as effective, and performs very much the same way as the predicate device, Applied SI Suction Irrigator. It also has the same design, performance and structure as predicate device. Hence it is substantially equivalent to the predicate device.

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

MAY 19 2010

Modern Medical Equipment Manufacturing, Ltd.
% Mr. Eugene Yeung
Assistant Regulatory Manager
5F, Gold King Ind. Building
35 Tai Lin Pai Road
Kwai Chung, Hong Kong, China

Re: K093479
Trade/Device Name: Disposable Suction and Irrigation System
Regulation Number: 21 CFR 876.4370
Regulation Name: Gastroenterology-urology evacuator
Regulatory Class: Class II
Product Code: FHF
Dated: April 09, 2010
Received: April 13, 2010

Dear Mr. Yeung:

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

Indication for Use Statement

Applicant: Modern Medical Equipment Manufacturing Ltd.

510(k) Number ~~Not assigned yet~~ K093479

Device Name: Disposable Suction And Irrigation System

Indications For Use:

The Disposable Suction And Irrigation System is used to deliver sterile irrigation fluids to surgical sites during laparoscopic procedures and to remove fluid waste, tissue debris and smoke from the surgical site.

Prescription Use ✓ AND/OR Over-The-Counter Use ____
(Part 21 CFR 801 sub-part D) (Part 21 CFR 807 sub-part 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 K093479