K052797

FEB 13 2006

V Leader in Smoke Plume Evacuation and Aerosol Management™

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Buffalo, NY 14228
(800) 343-2324
(716) 835-7000
(716) 835-3414 fax
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Info@buffalofilter.com

510(k) SUMMARY

Buffalo Filter
595 Commerce Drive
Buffalo, NY 14228

Phone: (800) 343.2324
(716) 835.700
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Contact Person: Robert O. Dean

Date Prepared: September 30, 2005

Device Name: LapEvac, Filtration Device for the Pneumoperitoneum

Common Name: Smoke Evacuator

Classification Name: Apparatus, exhaust, surgical
878.5070

Predicate Device: Sun Medical SFE-200
Sun Medical Smoke Evacuator Circuit
Reviewed and released under 510(k) 91154/A

Member Of:
American Society for Quality
ASQ

ISO 9001 – ISO 13485
UL
0E2
BUFFALO FILTER A12634
REGISTERED

K052797

Device Description:

LapEvac is a battery operated smoke evacuation system that connects directly to the inlet and outlet cannula/ trocars and creates a continuous closed circuit for filtering pneumoperitoneum gaseous media (typically CO_2). The system contains the LapEvac unit and connection tubing. Filtration is accomplished using activated charcoal filtration media and ULPA filtration media. The system filters and recirculates at an approximate rate of 4 liters per minute. Operating life is approximately 4 hours. A 3 amp, UL rated slide switch provides on/off control.

Intended Use:

To remove airborne particles generated by tissue combustion during laparoscopic surgery, via filtration of gaseous media contained within the distended pneumoperitoneum in order to significantly improve visualization. LapEvac may be used in any laparoscopic surgery, as appropriate.

Sterile, single use only device

Technological Comparison

Similarities of LapEvac and the predicate include the intended/indications for use – both devices are used in laparoscopic surgeries to filter pneumoperitoneum gas for removing smoke particles and thereby significantly increasing visualization within the pneumoperitoneum. The operating principle of the two devices is the same - the active recirculation of pneumoperitoneum gas and filtration through similar sub-micron sized filters.

Power supplies differ. LapEvac is battery operated at 6 volts versus 120volt AC for the predicate device.

Performance Data: Three sets of bench verification tests were conducted.

Clarity of View and Evacuation Efficiency verified LapEvac's ability to clear smoke from the chamber in a time comparable to smoke filtration devices commonly used during laparoscopic surgeries.

Effect on Pneumoperitoneum verified that LapEvac has no effect on the pneumoperitoneal pressure, temperature, and relative humidity.

Power Budget verifies power consumption and assures that LapEvac operation exceeds 4 hours.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 13 2006

Mr. Robert O. Dean
Vice President
Medtrek Devices, Incorporated
595 Commerce Drive
Buffalo, New York 14228

Re: K052797
Trade/Device Name: LapEvac, Filtration Devices for the Pneumoperitoneum
Regulation Number: 21 CFR 878.5070
Regulation Name: Air-Handling Apparatus for Surgical Operating Room
Regulatory Class: II
Product Code: FYD
Dated: January 20, 2006
Received: January 25, 2006

Dear Mr. Dean:

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.

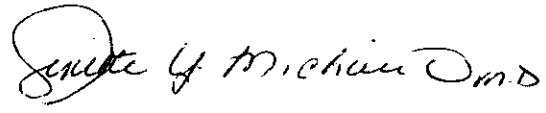
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (240) 276-. 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/industry/support/index.html..

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K052797

Device Name: LapEvac, Filtration device for the pneumoperitoneum

Indications For Use:

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LapEvac may be used in any laparoscopic surgery, as appropriate.

Sterile, single use only device

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)

Sheila A Murphy MD 1/10/06

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