McGan Technology

OCT 1 2010

510(k) Summary

Submitter Name Address:	Jack Ganis
Submitter Name Address:	McGan Technology, LLC 410 Ridge Rd Middletown, CT 06457 USA
Phone Number:	508-876-1070
Fax Number:	508-883-3434
Name of contact person:	Jack Ganis
Date Summary Prepared:	September 3, 2010
Proprietary Name:	MicroMed PD-8K (MMPD-8K)
Common Name:	Insulation Tester
Classification Name:	Gynecologic laparoscope and accessories 21 CFR 884.1720 Unipolar endoscopic coagulator-cutter and accessories 21 CFR 884.4160 Endoscope and accessories 21 CFR 876.1500
Device Classification:	Class II per 21 CFR 884.1720 and 844.4160 and 876.1500
Panel Code:	85

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Predicated Device accessory:

LIT Insulation Testing system
(K952889)

InsulScan™ Electrosurgical
Instrument Insulation Testers
(Mobile Instruments)
(K991424)

ATI-014 Insulation and
Continuity Tester
Jac-cell Medic Canada
(K020334155)

Intended Uses/indications:
The MicroMed PD-8K system is a non-destructive, non-patient contact, high voltage insulation tester designed to test the insulation integrity of electrosurgical instruments.

Device Specifications:

- Weight: 2.2kg (4.85 lbs)
- Display: LCD
- Voltage: 0 to 8kV adjustable
- Resolution: 10V
- Current Output: < 0.1mA at probe
- Short Circuit: Test current 0.1mA max
- Power Supply: 3.5AH Lead Acid Gel Cell
- Dimensions: 260 x 160 x 70mm 10.25 x 6.3 x 2.75 inches
- Alarm: Audible and Visual
- Frequency DC
- Fuse Replaceable in control unit

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Product Components:

The MicroMed PD-8K system (MMPD-8K) is comprised of a reusable hand-held instrument probe, a detector or control/base unit, a ground wire and a high voltage wire in which the appropriate electrode (instrument probe) is connected to. The MicroMed PD-8K system is powered by a rechargeable battery housed at the end of the detector (control/base) unit. The battery adaptor (recharger) is provided with the system for recharging the battery. The MicroMed PD-8K electrodes are reusable.

MicroMed PD-8K System includes:

- Detector (base unit)
- Battery with Charging adaptor
- Probe handle with 2m (6ft) lead-Red HV Wire
- 2m (6ft) lead ground wire with clamp-Green Wire
- Brush electrode - 8mm (0.31inch) wide brass wires
- Ring Electrode with brass wires
- Carrying case
- Standard Operating Instruction manuals. CD With additional information.

The MicroMed PD-8K system, the InsulScan™ Electrosurgical Instrument Insulation Testers (Mobile Instruments) and ATI-014 Insulation Continuity Tester by Jac-Cell have the same indications for use, similar designs, all are battery operated and rechargeable.

Device/Predicated	MicroMed Pd-8K	Insulscan	Jac-Cell
Indications for use	Insulation /Continuity testing	Insulation /Continuity testing	Insulation /Continuity testing
Design	Tester and accessories	Tester and accessories	Tester and accessories
Materials	Plastic housing	Aluminum Casing	Aluminum Casing
Performance	Voltage Insulation Tester	Voltage Insulation Tester	Voltage Insulation Tester
Sterility	N/A	Probes and wires	N/A
Usage	Pre-operating room	Pre-operating room or in the operating theater	Pre-operating room
Biocompatibility	Not required- Non patient contact.	Not required- Non patient contact.	Not required- Non patient contact.
Target population	Pre-operation nurses or central sterile personnel	Pre-operation nurses	Pre-operation nurses or central sterile personnel
Mechanical Safety	Accessory to a device	Accessory to a device	Accessory to a device

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Testing of Electrosurgical instruments

McGan recommends the use of the MMPD-8K System after the electrosurgical instrument has been fully cleaned according to the instructions from the manufacturer of the electrosurgical instrument or the hospital's standard procedure BUT before sterilization of the instrument.
This will eliminate any potential to cross-contaminate the surgical instrument.

Manuals

Please contact McGan Technology for copies of the user manuals for the MicroMed PD-8K System

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Mr. Jack Ganis
Director/Owner
McGan Technology, LLC
410 Ridge Road
MIDDLETOWN CT 06457

OCT 1 2010

Re: K101606
Trade Name: MicroMed PD-8K (aka MMPD-8K), MMUNI-0002 (base unit part number
Regulation Number: 21 CFR §884.4160
Regulation Name: Unipolar endoscopic coagulator-cutter and accessories
Regulatory Class: II
Product Code: HFG
Dated: September 24, 2010
Received: September 27, 2010

Dear Mr. Ganis:

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.

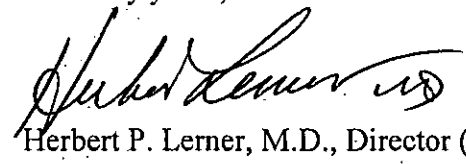
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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,



Herbert P. Lerner, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal
and Urological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Indications for Use

510(k) Number: K101606

Device Name: **MicroMed PD-8K (aka MMPD-8K), MMUNI-0002 (base unit part number)**

Indications for Use:

The MicroMed PD-8K kit or system is a non-destructive, non-patient contact, high voltage insulation tester designed to test the insulation integrity of electrosurgical instruments.

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K101606

Over-the-Counter Use ✓