K053510

MAR 2 0 2006

LINEMASTER®
AMERICA'S FOOT SWITCH LEADER

510K SUMMARY OF SAFETY AND EFFECTIVENESS DATA

General Information

Manufacturer:

Linemaster Switch Corporation
29 Plaine Hill Road
Woodstock, CT 06281
860-974-1000 Phone
860-974-1533 Fax

Establishment Registration Number:

???????????

Contact Person:

Michael W. Szostek
Components/Safety Engineer
mszostek@linemaster.com

Date Prepared:

December 1, 2005

Classification Name:

Endoscope and Accessories
Bone Cutting Instruments and Accessories.
Electrosurgical Cutting and Coagulation Device and Accessories.
General and Plastic Surgery
Any class II device that uses a foot switch as an accessory.

Common and Usual Name:

Wireless Foot switch

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Proprietary Name:

IR Wireless Foot Switch

Predicate Devices:

The Linemaster infrared wireless footswitch is substantially equivalent in function and intended use to the following legally marketed devices: Applied Surgical, LLC, Gemini Surgical and Display System (K051831), Stryker wireless universal footswitch (K033135), SurgASSIST system with wireless remote control (K020343), Megadyne Mega power electrosurgical generator accessories (K050579) and Valleylab force FXc accessories (K944602).

Device Description:

The Linemaster wireless foot switch will be an accessory to and provide foot switch input control to any medical device that uses a foot switch to control on/off inputs. The system includes a wireless foot switch and a receiver. The wireless foot switches share the same transmission schemes, however each manufacturer will have a unique identification code that is programmed into the transmitter and receiver. This identification code will only allow communication of systems that have been programmed with the same identification code. Systems from different manufacturers will not communicate with each other.
When coupled with a system that uses a wired foot switch the wireless system will function in the same way as the wired version. Apart from the software, the technological characteristics are the same or similar to, those of the predicate wired device where LED-based systems and infrared signals are used to operate the device.
The elimination of wires on the floor of the operating room will improve the safety and efficiency by uncluttering the OR floor and reducing set-up and clean-up time.

Performance Data:

The infrared wireless foot switch system meets the following standards:

- Classified to IEC/UL 60601.1 Medical electrical equipment by Underwriter's Laboratories, Inc with respect to fire, shock, and mechanical hazards in accordance with IEC/UL 60601.1.
- Classified with respect to electric shock, fire, mechanical, and other specified hazards only, in accordance with Can/CSA C22.2 No. 60601.1

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- EN60601-1-2: 2001
- IEC 1000-4-2: 1995 Electrostatic Immunity
- IEC 1000-4-3: 1995 Radiated Electromagnetic Field Immunity @ 10uv/m
- IEC 1000-4-4: 1995 Electrical Fast Transients Immunity
- IEC 1000-4-5: 1995 Surge Immunity
- IEC 1000-4-6: 1996 Conducted RF Immunity
- IEC 1000-4-8: 1993 Power Frequency Magnetic Field Immunity
- IEC 1000-4-11: 1994 Voltage Dips and Variations
- EN 55011: 1998 Radiated and Conducted Emissions, Group 1 Class B
- FCC Part 15 Radiated and Conducted Emissions, Class B
- IEC 61000-3-2: 2000 Power Harmonics Class A
- IEC 61000-3-3: 1995 + A1: 2001 Voltage Fluctuation, Section 5

The safety and effectiveness of the wireless footswitch described in this submission has been demonstrated through risk analysis, verification, and validation testing.

Indications for Use:

The Linemaster wireless foot switch will be an accessory to and provide foot switch input control to any medical device that uses a switch closure (on/off), to activate said device.

Warnings:

Plasma video displays can seriously affect the operation of infrared devices. The plasma devices can increase switch activation times significantly or prevent the switch operation altogether.
Do not use in the vicinity of plasma video displays.

Summary of Technological Characteristics:

The infrared wireless foot switch in this submission is similar with regard to design, operation, and materials and intended use to the predicate devices indicated above. Therefore, no new safety or efficacy issues are created and the wireless foot switch is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 0 2006

Linemaster Switch Corporation
c/o Mr. Michael W. Szostek
Component/Safety Engineer
29 Plaine Hill Road
Woodstock, Connecticut 06281

Re: K053510
Trade/Device Name: IR Wireless Foot Switch
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: March 10, 2006
Received: March 13, 2006

Dear Mr. Szostek:

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.

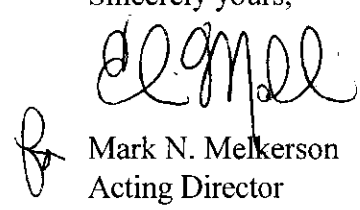
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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) 276-0120. 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/dsma/dsmamain.html

Sincerely yours,



Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number : (K053510)

Device Name: IR Wireless Foot Switch

Indications For Use:

The Linemaster wireless foot switch is an accessory that is indicated for use to provide foot switch input control to any medical device that uses a wired foot switch with a switch closure (on/off), to activate said device.

The system is intended for use in hospitals, outpatient clinics and physicians offices.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 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 General, Restorative, and Neurological Devices

510(k) Number K053510