JAN 2 1 2004

K040015 (pg 1 of 3)

510(k) SUMMARY

ALM PrismAlix® (PRX) Surgical Light with Energix™ Power Supply

Submitted by: Getinge USA, Inc. (as ALM S.A.'s US Agent)
1777 E Henrietta Road
Rochester, NY 14623-3133

Contact Person: Frederick R. Catt
Senior Regulatory Engineer
Phone: (585) 272-5013
Fax: (585) 272-5299

Date prepared: December 31, 2003

Proprietary Name: ALM PrismAlix® (PRX) Surgical Light

Common Name: Surgical Light

Device Classification: Surgical Lamp (78 FSY)

Class II, as listed per 21 CFR 878.4580

Predicate Device: ALM PrismAlix® (PRX) Series Surgical Light [K982063]

Description of Modified Device:

The PrismAlix® (PRX) Surgical Light System is an existing product line that will allow modification via the use of an updated Energix™ Power Supply as its means to control the surgical lighthead illumination levels. The updated Energix™ Power Supply contains software that enables additional features and capabilities not available on the earlier version of Energix™ Power Supplies. These include:

a) The power supply and regulators,
b) one or two touch-pad units that provide the user the ability to:
   i) turn on/off one or two lightheads,
   ii) adjust illumination intensity levels and
   iii) additional Light Emitting Diodes (LEDs) are used to indicate:
      (1) the illumination level,
      (2) bulb failure sensing and
      (3) power supply mode: Mains supply: green LED or the switching to a battery back-up system results in the LED indicator changing its color to red.

K040015 (pg 2 of 3)

An optional RS232 Communication Motherboard is also a new feature that allows shifting controls to a remote site within a specified distance (50m, 164 ft.) away from the surgical light. With the RS232 board, users also are provided specific user and maintenance type information/data, displayed on a Liquid Crystal Display (LCD) window located on the front panel of the Energix™ power supply. The user also has an option to have data communicated to a personal computer (PC).

The LCD can show information about preventive maintenance type items, including:

1. programming of maintenance inspections
2. storage of operating parameters
3. hours of operation
4. bulb life data
5. self-diagnosis information
6. direct reading of parameters – voltage, current, temperature
7. traceable management data – serial number, software version number, production and service dates)

Table 1

Energix™ Power Supply – Designations/Configurations				
Model				**Description**
WPS443				**Example: WPS Power Supply with two 360W Power Modules, two keypads and a RS232 Communication Motherboard**
WPS				Base Model Designation [Transformer; plus filter PCB and regulator(s)]
	2			150W Power Module and control keypad
	4			360W Power Module and control keypad
		0		Space holder – No #2 Power Module and 2nd control keypad (single lighthead)
		2		150W Power Module #2 and 2nd control keypad
		4		360W Power Module #2 and 2nd control keypad
			0	Power Module(s) only
			1	Power Module(s), RS232 Communication Motherboard and Battery Backup system/charger (Note: not currently planned for USA distribution)
			3	Power Module(s), RS232 Communication Motherboard

K040015 (pg 3 of 3)

Intended Use:
The PrismAlix® Surgical Light with the upgraded Energix™ Power Supply is intended to be used to provide visible illumination of the surgical area or the patient. The Energix™ Power Supply is intended for use with surgical light systems.

Nonclinical Comparisons to Predicate Device

The PrismAlix® Surgical Light with the upgraded Energix™ Power Supply (subject device) is similar to the predicate device with the following modifications:

- Replacement of the older Energix™ design with an upgraded Energix™ Power Supply (WPS) that includes use of software, and makes available a low energy remote touch-pad panel per lighthead.
- As the RS232 option, the Energix™ can provide the user with product condition type information via a LCD screen or interfacing with a remote PC.
- Software is incorporated within the Energix™ design, which interfaces with input signals sent from the dimmer control and ON/OFF lamp touch-pads. These switches provide output signals used by the intensity control regulator supplying voltage to the lamps (bulbs) within the corresponding lighthead.
- The Energix™ Power Supply can operate up to two lightheads, rated 360W each.

Test Data:

The test data supports conformance to:

- UL 2601-1 *Standard for Medical Electrical Equipment, Part 1: General Requirements for Safety*
- CSA C22.2 No. 601.1 *Medical Electrical Equipment, Part 1: General Requirements for Safety*
- IEC 60601-2-41 *Medical electrical equipment – Part 2-41: Particular requirements for the safety of surgical luminaires and luminaires for diagnostics*
- EN 60601-1-2 *Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests*
- Software used in the Energix™ Power Supply was tested according to the appropriate FDA Software Guidance Documents, per its determination as a Minor Level of Concern.

Clinical Data:

No clinical data is required for this device classification submission.

Conclusion:

Based upon the information provided herein this 510(k) Premarket Notification, we conclude that the ALM PrismAlix® (PRX) Series Surgical Light System using the updated Energix™ Power Supply is substantially equivalent to the predicate device(s) and is safe and effective when used as intended.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 21 2004

ALM S.A.
c/o Mr. Frederick R. Catt
Sr. Regulatory Engineer
Getinge USA, Inc.
1777 East Henrietta Road
Rochester, New York 14623

Re: K040015
Trade/Device Name: PrismAlix®(PRX) Surgival Light with Energix™ Power Supply
Regulation Number: 21 CFR 878.4580
Regulation Name: Surgical Lamp
Regulatory Class: II
Product Codes: FSY
Dated: December 31, 2003
Received: January 5, 2004

Dear: Mr. Catt:

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 (301) 594-4659. 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,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
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 (if known): **K040015**

Device Name: **PrismAlix® (PRX) Surgical Light with Energix™ Power Supply**

Indications for Use:

ALM S.A. PrismAlix® (PRX) Surgical Lights with Energix™ Power Supply are intended to be used to provide visible illumination of the surgical area or the patient. The Energix™ Power Supply is intended for use with surgical light systems.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

K040015