MAY 2 1 2004

K040735

510(k) SUMMARY

ALM X'Ten™ Surgical Light System

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:	March 19, 2004
Proprietary Name:	ALM X'Ten™ Surgical Light System
Common Name:	Surgical Light
Device Classification:	Surgical Lamp (78 FSY) Class II, as listed per 21 CFR 878.4580
Predicate Device:	ALM Angenieux® (AX) Series Surgical Light [K904965]

Description of Device:

The ALM X'Ten™ Surgical Light System is a new product designation intended to identify a family of surgical lights that will use a similar set of design principals as the Angenieux® (AX) Series Surgical Light Systems. The primary predicate device focuses on comparisons to the Angenieux® AX10, which is the medium sized lighthead within the Angenieux® (AX) Series.

The ALM X'Ten™ Surgical Light provides a broadened set of features and options that include video camera and flat screen display capabilities, bulb failure indicator(s), and an ambient light mode ("LEDinside") as results from this redesign effort. The user can toggle from the Surgical Light mode to the Ambient Light mode via use of a keypad switch

mounted on the yoke of the lighthead. The "LEDinside" mode presents a ring of light emitted from the bottom surface of the light, centered on the outer periphery of the sterile handle. Intensity can be adjusted to four levels: 30, 70, 110 and 150 Lux (@ 1m) and is sufficient to work on the patient in a dim or darkened operating room.

The ALM X'Ten™ Product Family currently has four configurations available, as shown within Table 1.

Table 1

ALM X'Ten™ Surgical Light and Systems – Designations/Configurations	
Model	**Description**
X10 DF	X'Ten™ SURGICAL LIGHT, CEILING MOUNTED, ONE X10 LIGHTHEAD
X10 duo DF	X'Ten™ SURGICAL LIGHT, CEILING MOUNTED, TWO X10 LIGHTHEADS
X10 duo DF V	X'Ten™ SURGICAL LIGHT, CEILING MOUNTED, TWO X10 LIGHTHEADS WITH ONE OF THOSE INCLUDING VIDEO PREWIRING AND AMBIENT LIGHT ("LEDinside" FUNCTION)
X10 duo DF V FS	X'Ten™ SURGICAL LIGHT, CEILING MOUNTED, TWO X10 LIGHTHEADS WITH ONE OF THOSE INCLUDING VIDEO PREWIRING AND AMBIENT LIGHT ("LEDinside" FUNCTION), AND ONE FLAT SCREEN SUPPORT

Note: Additional model configurations are planned for development. These will be incorporating use of the ALM X'Ten™ lighthead subassemblies.

Intended Use:

The ALM X'Ten™ Surgical Lights are intended to be used to provide visible illumination of the surgical area or the patient. The "LEDinside" ambient light mode is intended for minimally invasive surgeries, procedures and examinations.

Nonclinical Comparisons to Predicate Device

The ALM X'Ten™ Surgical Light (subject device) is similar to the predicate device with the following modifications:

- The ALM X'Ten™ Surgical Light uses the Energix™ Power Supply (WPS) to provide the electrical power to the light source. Surgical Light intensity levels are adjustable from the Energix keypad or remotely with RS232 communication port option. Bulb failure indicators provided. Optional LCD provides operation and maintenance information about the surgical light system, lightheads and bulbs.
- The ALM X'Ten™ introduces the "LED inside" option feature. This is an ambient light used to illuminate a larger patient area and is intended for minimally invasive surgery applications. Controls are located on the yoke keypad for switchover from Surgical Light to Ambient Light. "LED inside" light level adjustments are at 30, 70, 110 and 150 Lux.

- Added Capabilities of Video Camera (fixed focus or zoom), Multi-Media and Flat Screen Displays (Note: ALM X'Ten™ with "LED inside" feature is included) similar to the ALM PrismAlix® (PRX) Series Surgical Lights.
- Added an optional adapter for single use sterile sleeves/gloves on a standard handle system.
- Modified lighthead design, updating its appearance and suspension means.

Test Data:

The test data supports conformance to:

- UL 60601-1 *Standard for Medical Electrical Equipment, Part 1: General Requirements for Safety*
- UL60601-2-41 *Medical electrical equipment – Part 2-41: Particular requirements for the safety of surgical luminaires and luminaires for diagnostics*
- CSA C22.2 No. 601.1 *Medical Electrical Equipment, Part 1: General Requirements for Safety*
- CSA C.22.2 No. 60601-2-41 *Medical electrical equipment – Part 2-41: Particular requirements for the safety of surgical luminaires and luminaires for diagnostics*
- 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*
- FCC Part 15
- Software used in the ALM X'Ten™ Surgical Light 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:

The modifications incorporated into the ALM X'Ten™ Surgical Light System designs use those desired design features from both the ALM PrismAlix® (PRX) Series and Angenieux® (AX10) Surgical Light Systems. Based upon the information provided herein this 510(k) Premarket Notification, we conclude that ALM X'Ten™ Surgical Light Systems are 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

MAY 21 2004

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

Re: K040735
Trade/Device Name: ALM X'Ten™ Surgical Light System with Energix™ Power Supply
Regulation Number: 21 CFR 878.4580
Regulation Name: Surgical lamp
Regulatory Class: II
Product Code: FSY
Dated: April 30, 2004
Received: May 3, 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): K 040735

Device Name: ALM X'Ten™ Surgical Light System with Energix™ Power Supply

Indications for Use:

ALM X'Ten™ (X10) Surgical Light Systems with Energix™ Power Supply are intended to be used to provide visible illumination of the surgical area or the patient.

An optional "LEDinside" feature is available and produces lower intensity levels of ambient light, intended for minimally invasive surgery, procedures and examinations.

The Energix™ Power Supply is intended for use with surgical light systems.

Prescription Use ✓ 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

510(k) Number K040735