APR 2 3 2003

510(k) SUMMARY

ALM Axcel™ Surgical Light

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

Contact Person: Frederick R. Catt
Senior, Regulatory Engineer
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Date prepared: March 21, 2003

Proprietary Name: ALM Axcel™ 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® (PRX4000 Series) Surgical Light [K982063]
and
Angenieux (AX4) Surgical Light [K904965]

Description of Device:

The Axcel™ Surgical Light is a new product designation intended to identify a family of surgical lights that will use a similar set of design principals as the PrismAlix® (PRX) Series Surgical Light. The primary predicate device focuses on the PRX4000, which is the smaller lighthead within the PRX Series. Additionally, the Axcel light design also uses some design features from the Angenieux AX4 Surgical Light. Comparisons are made between it and these two predicate devices.

The current Axcel™ Family of Products and Configurations are shown in Table 1 below, along with their associated FDA Product Code(s). There are three configurations and comprise of two (2) ceiling mounted light system configurations (single and two lighthead) and one (1) wall mount system with one lighthead.

Table 1

Axcel™ Surgical Light Systems and Configurations		
Model	**Description**	**FDA Product Code(s)**
AXL 5001 S	Axcel™ Model AXL 5001 S is a ceiling mounted light system that contains one AXL 5000 Lighthead.	FSY/FQP
AXL 5002 S	Axcel™ Model AXL 5002 S is a wall mounted light system that contains one AXL 5000 Lighthead	FTD/FQP
AXL 5501 S	Axcel™ Model AXL 5501 S is a ceiling mounted light system that contains two AXL 5000 Lightheads.	FSY/FQP

Intended Use:

The Axcel™ Surgical Lights are intended to be used to provide visible illumination of the surgical area or the patient.

Nonclinical Comparisons to Predicate Device

The Axcel™ Surgical Light (subject device) is similar to the predicate device with the following modifications:

- Cosmetic changes to the lighthead, by rounding the overall shape and surfaces for improved laminar flow characteristics.
- Use of five (5) optical lens/windows, by adding one in the center of the cross layout design, while the Angenieux AX4 surgical light uses four lenses in a cross layout.
- Each Axcel™ lighthead incorporates a membrane switch panel that has an ON/OFF switch and illumination level adjustment switches (+ / --) that is ergonomically mounted within the handle (yoke post) of the lighthead assembly.
- The Axcel™ design incorporates the power supply and filter sub-assembly to be mounted into the suspension tube, rather than being mounted externally on the wall or ceiling.
- The dimmer control is mounted within the lighthead subassembly, near the membrane switch panel.
- Software is incorporated within the design, which interfaces with input signals sent from both the dimmer control and ON/OFF lamp membrane switches and provides output signals used by the dimmer control supplying voltage to the lamps (bulbs).

- The lighthead optical system uses a modified design from the AX4 lighthead system, by means of using similar microlens windows, central optical system and a similar four dichroic mirror sub-assembly.
- Axcel™ lights have a fixed focus and stationary light handle, whereas on both predicate devices, focusing means are provided.
- The Axcel™ light handle and post location is mounted slightly off-center in one axis, rather than being mounted in the direct center of the AX4 lighthead. The modified positioning provides an unobstructed space for the center (fifth) optical lens/window. The Axcel light incorporates the same sterilizable light handle as those used on the PRX surgical light.

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 Axcel™ 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 Axcel™ Surgical Light designs used those desired design features from both the ALM PrismAlix® (PRX4000 Series) and Angenieux AX4 Surgical Lights. Based upon the information provided herein this 510(k) Premarket Notification, we conclude that the ALM Axcel™ Surgical Light 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

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ALM S.A.
c/o Mr. Frederick R. Catt
Senior Regulatory Engineer
Getinge/Castle, Inc.
1777 E. Henrietta Road
Rochester, New York 14623-3133

Re: K030906
Trade/Device Name: ALM Axcel™ Surgical Light
Regulation Number: 21 CFR 878.4580
Regulation Name: Surgical Lamp
Regulatory Class: II
Product Code: FSY
Dated: March 21, 2003
Received: March 24, 2003

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. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. 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 may be obtained 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 STATEMENT

510(k) Number: K030906

Device Name: **Axcel™ Surgical Light**

Indications for Use:

ALM S.A. Axcel™ Surgical Lights are intended to be used to provide visible illumination of the surgical area or the patient.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K030906