K982063

SEP 22 1998

Summary of Safety and Effectiveness

Prismalix™ Surgical Light

June 11, 1998

INTENDED USE

ALM Prismalix™ (PRX) Surgical Lights are intended to provide visible illumination for the surgical field or for the examination of the patient. PRX is designed to eliminate shadow, reduce reflected heat, and illuminate surgical incisions of all depths during surgical procedures. The ALM Surgical Lights will be used in indications, which are the same as indications for other surgical lights currently offered for commercial distribution in the United States.

PRODUCT DESCRIPTION

ALM Surgical Equipment, Inc. has been selling Surgical Lights in the United States since July 1988. The products sold were and are manufactured by the parent company of ALM Surgical Equipment Inc., ALM SA, located in France. The Prismalix™ series continues to be manufactured by the parent organization, ALM SA.

The new product known as "Prismalix™" is of similar technology to surgical lights covered under D.C. Number K882613 issued on June 29, 1988. The differences between the new Prismalix™ models and models previously sold are cosmetic along with the addition of a tilting mechanism (in selected models) which allows variations in pattern size.

The surgical light consists of single or multiple lightheads attached to suspension arms supported from hospital installed mounting plates. Light heads can be positioned for optimal illumination of the surgical site by grasping sterilizable handles or non-sterile handles on the lighthead.

Low voltage power is supplied to the light bulb by way of a remote mounted transformer similar to those used by other surgical lighting manufacturers. Light intensity is controlled by a dimmer system, mounted remotely at a wall location.
Illumination is measured in footcandles or lux (1 footcandle equals 10.764 lux). *Reference publication RP-29-95 Lighting for Hospitals and Health Care Facilities chapter 4, section 11, page 18. Illuminating Engineering*

Society of North America, New York, NY 1995. IES recommends a minimum illumination level at the surgical site of 2,500 footcandles when the light is positioned one meter above the site. The Prismalix™ series meets and exceeds this recommendation.

The previous range of lighting covered under K882613 is referenced by the three sizes of light heads; 500 mm or 5000 series, 700mm or 7000 series, and 900mm or 9000 series. The Prismalix™ series will be referenced by three sizes of light heads; 400mm or 4000 series, 600mm or 6000 series, and 800mm or 8000 series.

It is possible to provide a fixed focus video camera in selected 4000 series light heads. This Prismavision camera is similar in overall design and construction to the current ALM fixed focus camera, and other surgical/endoscopic video cameras offered for commercial distribution in the United States.

Contained in Section II of this submission are brochures that provide photos and specifications of some of the various models offered as part of the PRX series. The design of the PRX series is similar in overall design and construction to the current ALM products; and other surgical lights with variable pattern sizes, offered for commercial distribution in the United States.

RATIONALE FOR SUBSTANTIAL EQUIVALENCE

The ALM Prismalix™ Surgical Light is substantially equivalent in - materials, design, and function to surgical lights currently in commercial distribution in the United States. Specifically, the ALM Prismalix™ Surgical Light is substantially equivalent to the following systems:

1. ALM Surgical Equipment, Inc.
   1820 North Lemon Street, Anaheim, CA 92801
   Reviewed by the FDA (K882613), 06/29/88

2. Berchtold Corporation,
   1950 Hanahan Road, Charleston, SC 29419
   Reviewed by the FDA (K922836), 10/09/92

3. Steris (Amsco)Corporation,
   5960 Heisley Road, Mentor, OH 44060,
   Reviewed by the FDA (K943288), 10/17/94

4. Midmark (Chick Surgical),
   Versailles, OH 45380
   Reviewed by the FDA (K860739), 03/28/86

All of these systems are ceiling, wall or mobile mounted surgical lights intended to provide acceptable levels of illumination to the surgical site.

All of these systems are modular in design to allow for maximum flexibility in meeting the needs of individual users during a variety of procedures.

The following charts provide a comparison of features of the ALM Prismalix™ Surgical Light to other similar commercially marketed systems.

Table I
ALM PRX compared to ALM ECL/PRC

	ALM PRISMALIX™	ALM PRISMATIC®
Intended Use	Illumination of surgical field.	Illumination of surgical field.
Components	Suspension Arms (1 to 3)	Suspension Arms (1 to 3)
	Spring Arms (1 to 3)	Spring Arms (1 to 3)
	Light Head (1 to 3)	Light Head (1 to 3)
	Dimmer Control (1 to 3)	Dimmer Control (1 to 3)
	Transformer (1 to 3)	Transformer (1 to 3)
	Lamps (1 to 3), per light head	Lamps (1 to 3), per light head
	Portable	Portable
	Wall Mount	Wall Mount
	Ceiling Fixture	Ceiling Fixture
Features and Technical Specifications	Halogen Lamp (23v, 100w)	Halogen Lamp (24v, 120w)
	360° Suspension Rotation	360° Suspension Rotation
	Sealed Light Head	Sealed Light Head
	Central Optical System	Central Optical System
	100,000 to 120,000 lux	55,000 to 120,000 lux
	Input Voltage 120v	Input Voltage 120v
	Low Voltage Consumption: 4 to 12 amps	Low Voltage Consumption: 5 to 15 amps
	Graduated Dimmer Controls	Graduated Dimmer Controls
	19" to 35" Light Head Diameter	20 to 36" Light Head Diameter
	Light Pattern Adjustment (5.5" to 11"), adjustment method, Manual	28" fixed column of light, 8" pattern.
	Reflector Type: Prisms	Reflector Type: Prisms

Table II
ALM compared to Berchtold

	ALM PRISMALIX™	Berchtold
Intended Use	Illumination of surgical field.	Illumination of surgical field.
Components	Suspension Arms (1 to 3)	Suspension Arms (1 to 3)
	Spring Arms (1 to 3)	Spring Arms (1 to 3)
	Light Head (1 to 3)	Light Head (1 to 3)
	Dimmer Control (1 to 3)	Dimmer Control (1 to 3)
	Transformer (1 to 3)	Transformer (1 to 3)
	Lamps (1 to 3), per light head	Lamps (2), per light head
	Portable	Portable
	Wall Mount	Wall Mount
	Video Camera	Video Camera
	Ceiling Fixture	Ceiling Fixture
Features and Technical Specifications	Halogen Lamp (23v, 100w)	Halogen Lamp (22.8v, 100-150w)
	360° Suspension Rotation	360° Suspension Rotation
	Sealed Light Head	Sealed Light Head
	Central Optical System	Central Optical System
	100,000 to 120,000 lux	90,000 to 150,000 lux
	Input Voltage 120v	Input Voltage 120v
	Low Voltage Consumption: 4 to 12 amps	Low Voltage Consumption: 5 to 11 amps
	Graduated Dimmer Controls	Graduated Dimmer Controls
	19" to 35" Light Head Diameter	17.5" to 37" Light Head Diameter
	Light Pattern Adjustment (5.5" to 11"), adjustment method, Manual	Light Pattern Adjustment (5.8" to 13.65"), adjustment method, Manual
	Reflector Type: Prisms	Reflector Type: Parabolic Reflector

Table III
ALM PRX compared to Steris (Amsco)

	ALM PRISMALIX™	STERIS (AMSCO)
Intended Use	Illumination of surgical field.	Illumination of surgical field.
Components	Suspension Arms (1 to 3)	Suspension Arms (1 to 3)
	Spring Arms (1 to 3)	Spring Arms (1 to 3)
	Light Head (1 to 3)	Light Head (1 to 3)
	Dimmer Control (1 to 3)	Dimmer Control (1 to 3)
	Transformer (1 to 3)	Transformer (1 to 3)
	Lamps (1 to 3), per light head	Lamps (2), per light head
	Portable	Portable
	Wall Mount	Wall Mount
	Ceiling Fixture	Ceiling Fixture
Features and Technical Specifications	Halogen Lamp (24v, 100w)	Halogen Lamp (22v, 220w)
	360° Suspension Rotation	360° Suspension Rotation
	Sealed Light Head	Sealed Light Head
	Central Optical System	Central Optical System
	100,000 to 120,000 lux	161,400 lux
	Input Voltage 120v	Input Voltage 120v
	Low Voltage Consumption: 4 to 12 amps	Low Voltage Consumption: 10 Amps
	Graduated Dimmer Controls	Graduated Dimmer Controls
	19" to 35" Light Head Diameter	24" Light Head Diameter
	Light Pattern Adjustment (5.5" to 11"), adjustment method, Manual	Light Pattern Adjustment (5.8" to 7.8"), adjustment method, Manual
	Reflector Type: Prisms	Reflector Type: Parabolic Reflector

Table IV
ALM PRX compared to Midmark (Chick)

	ALM PRISMALIX™	MIDMARK/CHICK
Intended Use	Illumination of surgical field.	Illumination of surgical field.
Components	Suspension Arms (1 to 3)	Suspension Arms (1 to 3)
	Spring Arms (1 to 3)	Spring Arms (1 to 3)
	Light Head (1 to 3)	Light Head (1 to 3)
	Dimmer Control (1 to 3)	Dimmer Control (1 to 3)
	Transformer (1 to 3)	Transformer (1 to 3)
	Lamps (1 to 3), per light head	Lamps (2), per light head
	Portable	Portable
	Wall Mount	Wall Mount
	Ceiling Fixture	Ceiling Fixture
	Halogen Lamp (23v, 100w)	Halogen Lamp (22.8v, 100-150w)
Features and Technical Specifications	360° Suspension Rotation	360° Suspension Rotation
	Sealed Light Head	Sealed Light Head
	Central Optical System	Central Optical System
	100,000 to 120,000 lux	55,000 to 107,000 lux
	Input Voltage 120v	Input Voltage 120v
	Low Voltage Consumption: 4 to 12 amps	Low Voltage Consumption: 5 to 11 amps
	Graduated Dimmer Controls	Graduated Dimmer Controls
	19" to 35" Light Head Diameter Light Pattern Adjustment (5.5" to 11"), adjustment method, Manual	17.5" to 37" Light Head Diameter Light Pattern Adjustment (5.8" to 7.8"), adjustment method, Manual
	Reflector Type: Prisms	Reflector Type: Parabolic Reflector

Safety Features

The ALM Prismalix™ Surgical Light described in this premarket notification was designed to meet criteria for Surgical Lighting as outlined in IEC 601-2-41 and manufactured using component materials accepted by Underwriters Laboratories.

360° rotation of the system's suspension arm and lighthead is made possible through the use of fully rotating electrical contacts, eliminating the possibility of twisting, binding and breaking of any internal wiring.

Each bulb in the lighthead is energized by 4 amps of low voltage power (23 volts).

Both sterile and non-sterile positioning devices are provided to maintain integrity of the sterile environment during surgical procedures.

All rotating joints in the suspension system are equipped with fully adjustable friction brakes to avoid unintentional movement after positioning of the lighthead for a procedure.

ALM has completed appropriate safety testing and has received *Notice of Authorization to Apply the UL and C-UL Marks* from Underwriters Laboratories, Inc., International Compliance Services on May 29, 1998. A copy of the notification is included in Section IV.

The PRX 4000, 6000, and 8000 series products referenced in this pre-market notification are identical to those referenced in the above letter by Underwriters Laboratories, Inc.

ADVERSE SAFETY AND EFFECTIVENESS INFORMATION

For correct and effective use of the ALM PRX Surgical Light and to avoid potential safety hazards, it is essential to follow the recommendations contained in the manuals provided with the device. Any use of the apparatus requires full understanding of user instructions. The apparatus is only to be used for purposes specified here.

Professional installation is required to ensure that all local standards and codes are met. Failure to meet these standards could result in injury or harm to patients and healthcare personnel.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 22 1998

Ms. Susan Nielsen
Director of Operations
ALM Surgical Equipment, Inc.
1820 North Lemon Street
Anaheim, California 92801

Re: K982063
Trade Name: ALM Prismalix (PRX) Surgical Light
Regulatory Class: II
Product Code: FSY
Dated: August 7, 1998
Received: August 11, 1998

Dear Ms. Nielsen:

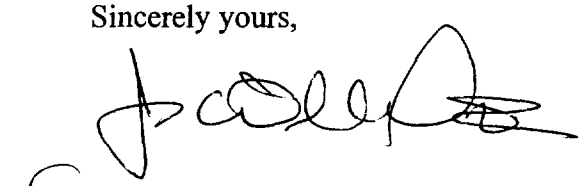
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. 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"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,



Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510K Number (if known): K982063

Device Name: ALM Prismalix (PRX) Surgical Light

Indications For Use: ALM Prismalix (PRX) Surgical Lights are intended to provide visible illumination for the surgical field or for the examination of the patient. PRX is designed to eliminate shadows, reduce reflected heat, and illuminate surgical incisions of all depths during surgical procedures. Use is by surgeons and other medical care givers.

The ALM PRX Surgical Lights will be used in indications which are the same as indications for other surgical lights currently offered for commercial distribution in the United States.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109

(Optional Format 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K982063