GETINGE Castle

Getinge/Castle, Inc.
7371 Spartan Blvd., East
North Charleston, SC 29418

Tel 803.552.8652
Fax 803.552.8652

K974084

510(k) Summary

(1)	**Submitters Name**	Getinge/Castle, Inc.
	Submitters Address	7371 Spartan Blvd., East North Charleston, SC 29418
	Submitters Telephone No.	(803) 552-8652
	Contact Name	Trevor Williamson
	Summary Preparation Date	October 3, 1997
(2)	**Device Name**	Getinge/Castle **OptiView©** Surgical Light
	Common or Usual Name	Surgical Light
	Classification Name	Surgical Lamp
(3)	**Predicate Device(s)**	ALM Prismatic©, model 7001 and 9001 series AMSCO SQ240 Berchtold Chromophare©, model C-570, C-570/570 and C-570/570/570
(4)	**Device Description**	The Getinge/Castle **OptiView©** surgical lights are designed to provide the high quality light required in an operating room setting. There are four major considerations that the lights have been designed for: 1. Shadow Elimination. 144 radial dioptric lenses, disposed equally on the lens glass, are used to broaden the light beam such that a 10 X 20 cm patch of light is produced on the surgical site from each lens. Should one or several of the lenses become obstructed by the surgeon or from equipment, a constant quantity of light is subtracted from each point of the light field. This virtually eliminates shadows and provides for optimum visibility. 2. Optimal Depth of Field. A central toric lens and conic mirror is used to produce very broad beams whose intersection are not points but are volumes. In some cases the volume can measure up to 70 cm in height and 20 cm across the center. The design also allows the volume of light to be moved in the axis of the beam, this is called true variable focusing. 3. Heat Elimination and High Color Rendition. Through the use of a special type of glass, the emitted light is corrected for color (towards the model for broadband sunlight) and filtered for infrared. This eliminates the thermal effect of the beam and allows a color rendition index of Ra = 95 or greater.

GETINGE Castle

Getinge/Castle, Inc.
7371 Spartan Blvd., East
North Charleston, SC 29418

Tel 803.552.8652
Fax 803.552.8652

(4) **Device Description (con't)**

4. Electromagnetic and Bacteriologic Neutrality. The product have been designed and tested to comply with the strictest electromagnetic compatibility standards. Also, the sealed optical unit, the flat, smooth surfaces and sensitive touch-controls provide for an extremely aseptic environment.

The mechanical aspects of the lights are that they are constructed of specifically designed steel load-bearing drop tubes, yokes and suspension assemblies that are coated with a strong epoxy resin paint. These structures are mechanically connected at pivot points that incorporate counter-balances for ease of movement as well as specially designed wire-runs and fully pivoting electrical connectors.

The electrical aspects of the lights are designed* to comply with international safety standards such as:

5. Low Voltage Directive (LVD) 72/23/CEE, Decree No. 95-1081
6. Electromagnetic Compatibility Directive (EMC) 89/336/CEE, Decree No. 95-587
7. Medical Device Directive (MDD) 93/42/CEE, Power Supply Units, NF EN 60-4391 (IEC 433-1), NF EN 60-439-4
8. Operating Theatre Lighting, NF EN 60-601-1 (IEC 601)

The design will also be examined to UL 544 and certified by either Underwriters Laboratory or Intertek Testing Services (ITS) which should result in the UL or ETL mark.

***NOTE: The lights were previously CE marked, while marketed in Europe, by the original manufacturer: Scialityque Industrie.**

The lights are electrically controlled via pressure sensitive touch controls that may be located on the lights or at remote locations. The controls allow the lights to be energized, the light level to be adjusted and the focus mechanisms to be operated.

The light beam is achieved through the use of one or two (dependent upon model) tungsten-halogen 24 VDC bulbs that are contained in a sealed optical unit. The emitted light is focused through a toroidial lens and is reflected off of a conic, polished aluminum reflector and through 144 radial dioptric lenses which allows for a radial-focused broad-beam light pattern on the surgical surface. This eliminates shadows while concurrently extending the true depth of field of the beam.

GETINGE Castle

Getinge/Castle, Inc.
7371 Spartan Blvd., East
North Charleston, SC 29418

Tel 803.552.8652
Fax 803.552.8652

(5)	**Statement of Intended Use**	The Getinge/Castle **OptiView©** Surgical Lights are to be used in the same, (general type and configuration), surgical operatory theatres, and out-patient surgery centers that currently employ various models of the referenced predicate devices.
(6)	**Summary of Similar Technology**	See attached product comparison tables. The specific models shown in the tables were chosen on the basis of the similarity of the lamp head designs, illumination and other performance data.

The **OptiView© 500** series lights are identified as follows:

Model	Description	Predicate
500	Ceiling mount – one (1) 500 series lamp head	ALM PRC 7001, Berchtold C-570/570
525	Ceiling mount – one (1) 200 series lamp head and one (1) 500 series lamp head	ALM PRC 7001, Berchtold C-570/570
550	Ceiling mount – two (2) 500 series lamp heads	ALM PRC 5501 DF, Berchtold C-570/570
555	Ceiling mount – three (3) 500 series lamp heads	ALM PRC 5551, Berchtold C-570/570
590	Floor stand mount – one (1) 500 series lamp head	ALM PRC 7001, Berchtold C-570/570

The **OptiView© 700** series lights are identified as follows:

Model	Description	Predicate
700	Ceiling mount – one (1) 700 series lamp head	ALM PRC 9001, AMSCO SQ240, Berchtold C-570/570/570
750	Ceiling mount – one (1) 500 series lamp head and one (1) 700 series lamp head	ALM PRC 9501 DF, AMSCO SQ240, Berchtold C-570/570/570
755	Ceiling mount – two (2) 500 series lamp heads and one (1) 700 series lamp head	ALM PRC 9551, AMSCO SQ240, Berchtold C-570/570/570

The basic assumptions that we are basing this pre-market notification on, and why we believe that the Getinge/Castle **OptiView©** Surgical Light is substantially equivalent to the predicate devices, is that we believe that:

- We are not introducing new technology. The **OptiView©** lights and the predicate devices use very similar technology to achieve the same basic goal; to illuminate the patient area and concentrate light at the surgical incision with deep cavity penetration. The use of the toric lens, conic reflector and radial dioptric lens in the 500 and 700 series has been standard practice for Scialytique (the original manufacturer) for over ten (10) years in Europe.

GETINGE Castle

Getinge/Castle, Inc.
7371 Spartan Blvd., East
North Charleston, SC 29418

Tel 803.552.8652
Fax 803.552.8652

- We are not introducing new or radical manufacturing methods. The Getinge/Castle **OptiView©** surgical lights will be manufactured using production methods readily available to the general medical device industry. These practices are already in use for existing domestically marketed products and will be used for the manufacture of the **OptiView©** 500 and 700 series lights.

- We are not introducing any new indications for use. As stated earlier, the Getinge/Castle **OptiView©** surgical lights are to be used for the same purposes and in the same manner as the predicate devices. The lights will be used as the primary and secondary methods of illuminating areas of the human body such that deep cavities can be penetrated and shadows eliminated during surgical procedures. Our intended customer base includes various health care professionals working in medium to large operatory settings.

We consider the **OptiView©** lights to be a single product line and we intend to market them in that manner. We have included them together for this notification because we believe that, like the ALM Chromophare© product line, which incorporates several different lamp head configurations under the same FDA clearance number, the **OptiView©** lights are contemporary and complimentary to each other. These lights will be used in different configurations as stand alone units but also will be combined together (i.e. the 500 series lamp paired with a 700 series lamp on the same suspension package) for total operatory coverage.

Part 2:

Predicate devices for the Optiview Series 200, with the requested specifications:

Specification	Model		
	Optiview 200 Series	ALM Illuminator Spotlight	Berchtold Chromophare C-300
Diameter, cm (in)			
Lens	230 (9.0)	Not specified	365 (10.4)
Lighthead	316 (12.4)	330 (13)	300 (11.8)
Weight, kg (lb.)	2.5 (5.5)	Not specified	Not specified
Mounting Type	Wall, Ceiling, Floor Stand	Wall, Ceiling, Floor Stand	Wall, Ceiling, Floor Stand
Supply Voltage, VAC	120/230	120	110/220
Power, W	55	150	55
Bulb, Type	Tungsten Halogen	Quartz Halogen	Halogen
Volts	24	Not specified	24
Life, hr	500	Not specified	Approx. 1000
Number of Light Heads	1	1	1
Number of Bulbs	1	1	1
Color Temp, °K	4300, Nominal	Not specified	4500
Field Size, cm (in)			
Diameter	100-150 (3.9-5.9)	Not specified	170 (6.7)
Depth	400 (15.7)	Not specified	Not specified
Focal Length, cm (in)	350 (13.8)	Not specified	Not specified
Illumination Level, ft-candles (Lux)	5,670 (61,000) at 4300°K	3717 (40,000)	3253 (35,000)
Controls			
Dimmer	Variable Intensity	Not specified	Not specified
Volts	24	Not specified	24
Focus	Adjustable	Not specified	Adjustable
Field Size	Adjustable	Not specified	Adjustable
Rotation, °	360	Not specified	360
Vertical Adjustment Range, cm (in)	1792 (70.5)	Not specified	1190 (46.9)
Heat Filtering, %	99	Not specified	Not specified
Filter Material	Glass	Not specified	Yes
Reflector Material	Polished Aluminum	Not specified	Not specified
Satellites	Optional	Optional	Not specified
Sterilizable Handle	Yes	Not specified	Not specified
Min. Ceiling Height, cm (in)	2591 (102)	Not specified	Not specified

GETINGE Castle

Getinge/Castle, Inc.
7371 Spartan Blvd., East
North Charleston, SC 29418

Tel 803.552.8652
Fax 803.552.8652

OptiView© 500 series vs. Predicate Devices

Model / Spec.	OptiView©, 500 series	ALM, PRC 7001 series	Berchtold, C-570 series
Diameter, cm (in)			
Lens	44.3 (17.5)	71.1 (28)	50 (20)
Lighthead	54.2 (21.3)	71.1 (28)	57 (22.5)
Weight, kg (lb.)	12 (26.4) lamp head only	73.9 (163) lamp head only	63 (138) single, 95 (209) dual
Mounting Type	Ceiling, wall, floor stand	Ceiling	Ceiling, wall, floor stand
Supply Voltage, VAC	120/230	120	120/230/240
Power, W	140	240	150
Bulb, Type	Tungsten Halogen	Quartz Halogen	Xenon Halogen
Volts	24	24	24
Life, hr	500 (min)	1000	1000
Number of Light heads	1, 2 or 3	1	1,2 or 3
Number of Bulbs	1 or 2	2	1 main, 1 reserve
Color Temp, °K	4,300	3,500	4,500
Field Size, cm (in)			
Diameter	10-15 (3.9-5.9)	20.3 (8)	18-28 (7-11)
Depth	40 (15.7)	70 (27.6)	80 (31)
Focal Length, cm (in)	90-140 (35-55)	Not specified	70-140 (27.5-55)
Illumination Level, max ft-candles (lux)	12,300 (130,000)	9,300 (100,000)	9,300 (100,000) 13,530 (145,000)
Controls			
Dimmer	Variable intensity	Continuous	Continuous
Volts	24	120	120
Focus	Adjustable	Fixed	Adjustable
Field Size	Adjustable	Fixed	Adjustable
Rotation, °	360	360	360
Vert. Adjustment Range, cm (in)	122.6 (48.3)	83.8 (33)	115 (45)
Heat Filtering, %	99	Not specified	99
Filter Material	Glass	Glass	Glass/film
Reflector Material	Aluminum	N/A (refracted through prisms)	Aluminum
Satellites	Optional	Optional	Optional
Sterilizable Handle	Yes	Yes	Yes
Min. Ceiling Height, cm (in)	245 (100)	264.2 (104)	260 (102)

GETINGE Castle

Getinge/Castle, Inc.
7371 Spartan Blvd., East
North Charleston, SC 29418

Tel 803.552.8652
Fax 803.552.8652

OptiView© 700 series vs. Predicate Devices

Model / Spec.	OptiView©, 700 series	ALM, PRC 9001 series	AMSCO, SQ240
Diameter, cm (in)			
Lens	58.5 (23)	91.4 (36)	55.9 (22)
Lighthead	75.6 (29.8)	91.4 (36)	60.9 (24)
Weight, kg (lb.)	28 (61.6)	21.8 (48) light unit only	67 (148) single, 113 (250) dual
Mounting Type	Ceiling	Ceiling	Single or dual arm, track, optional AV arm
Supply Voltage, VAC	120/230	120	120
Power, W	140	120	220
Bulb, Type	Tungsten Halogen	Quartz Halogen	Quartz Halogen
Volts	24	24	22
Life, hr	500 (min)	1000	1000
Number of Light heads	1,2 or 3	1	1,2 or 3
Number of Bulbs	1 or 2	3	1 main, 1 reserve per lighthead
Color Temp, °K	4,300	3,500	4,200; 4,400
Field Size, cm (in)			
Diameter	17-24 (6.7-9.4)	20.3 (8)	16.5 (6.5); 17.8 – 21.6 (7-8.5)
Depth	50 (19.7)	70 (27.6)	66 (26)
Focal Length, cm (in)	50 (19.7)	Not specified	106.7 (42)
Illumination Level, max ft-candles (lux @ 1 m)	11,200 (120,000)	11,160 (120,000)	10,000 (107,640) 12,000 (129,170
Controls			
Dimmer	Variable intensity	Continuous	Variable intensity
Volts	24	120	24
Focus	Adjustable	Fixed	Fixed
Field Size	Adjustable	Fixed	Adjustable
Rotation, °	360	360	360
Vert. Adjustment Range, cm (in)	122.6 (50)	134.6 (53)	74.9 – 200.1 (29.5 – 79)
Heat Filtering, %	99	Not specified	98
Filter Material	Glass	Glass	Cold/hot mirror; cold mirror
Reflector Material	Aluminum	N/A (refracted through prisms)	Plastic
Satellites	Optional	Optional	Optional
Sterilizable Handle	Yes	Yes	Yes
Min. Ceiling Height, cm (in)	245 (100)	281.9 (111)	257.8 (101.5) single 269.2 (106) dual

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 3 1998

Mr. Peter L. Koste, Jr.
Senior Manager, Quality Assurance and Regulatory Affairs
Getinge/Castle, Incorporated
7371 Spartan Boulevard, East (29418)
P.O. Box 40488
North Charleston, South Carolina 29423-0488

Re: K974084
Trade Name: Getinge/Castle Optiview Series Surgical Light
Regulatory Class: II
Product Code: FSY
Dated: January 27, 1998
Received: February 13, 1998

Dear Mr. Koste:

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 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 requirement, 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/dsmamain.html".

Sincerely yours,

for 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

510(k) Number (if known): K974084

Device Name: OPTIVIEW SURGICAL LIGHT

Indications For Use:

THE PRODUCT WILL BE USED TO ILLUMINATE SURGICAL PROCEDURES WITH COLOR CORRECTED LIGHT AND HEAT FILTERING (IR). THE PRODUCT IS DESIGNED TO ELIMINATE SHADOWS AND TO PENETRATE DEEP CAVITY WOUNDS WITH ADEQUATE LIGHTING.
THE PRODUCT IS INTENDED TO BE USED BY SURGEONS AND OTHER MEDICAL CARE PRACTICIONERS IN A SURGICAL SETTING. THERE ARE NO CONTRA-INDICATIONS FOR USE.

(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 Devices
510(k) Number K974084

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)