APR 29 1998

510(k) Summary

K981081

March 20, 1998

Applicant:

Hill-Rom, Inc.
1069 St. Route 46 East
Batesville, IN 47006
Reg. No: 1824206

Contact Person:

William D. Jordan
Ph: (812) 934-7471
Fx: (812) 934-1675

Device trade/proprietary name:

BRIGHTSTAR©

Device common/usual/classification name:

Surgical Light

Classification:

General and Plastic Surgery Devices
21 CFR 878.4580, Surgical Light,
79 FSY, Class II

Performance Standards:

Performance Standards for the device have not been established under Section 514 of the FD&C Act.

Predicate (Current) Device:

Amsco SQ240 Surgical Light
Berchtold Chromophare

Device Description

The light is available in a single, double or 3 light head version. Each model offers the option of wall controls, integrated light controls or a combination of both.
The light from a single bulb is distributed off a reflector in a controlled manner to provide a defined pattern. The size of the pattern is adjusted by changing the focal point of the bulb relative to the reflector.

The light is comprised of seven main components:

(I) Suspension Arm
(II) Extension Arm
(III) Counterbalance Arm
(IV) Yoke
(V) Light Housing
(VI) Light Core
(VII) Controls

(I) Suspension Arm

The Suspension Arm is attached to the ceiling about a central pivot point. The pivot provides a 360° motion allowing the arm to rotate in a full circle adjacent to the ceiling. Multiple arms can be mounted about the same point to facilitate mounting 1,2 or 3 lights.

(II) Extension Arm

The Extension Arm connects vertically to the Suspension Arm. The length of the Extension Arm can be adjusted to suit the various ceiling heights. It provides the means to control the head clearance between the floor and the underside of the lamp.

(III) Counterbalance Arm

The Counterbalance Arm pivots about the Extension Arm. It provides a radial motion of 105°. The Counterbalance can assume an infinite number of positions and will remain where it is positioned. The stability of the arm is achieved utilizing a spring balance that is concealed within the arm and fastened to a pivot that is off center from the elbow joint.

(IV) Yoke

The Yoke is connected directly to the end of the Counterbalance Arm and is free to rotate 360° in same plane as the arm. The Yoke supports the Light Housing permitting it to rotate freely about the two points of contact. Also located within the Yoke is the Task Light. The Task Light is used for background lighting during procedures when the main surgical light is not in use.

(V) Light Housing

The Light Housing incorporates the optical system that generates the light output. The concentric reflector has individual facets formed into the reflective surface. Each facet has been angled to focus the light toward a common focal point. The Reflector is comprised of two layers of aluminum with the inner surface being made up of pure aluminum. The highly polished finish is achieved by vacuum metalizing the inner surface.

The lens defuses the light to provide a shadow free, uniform image.

(VI) Light Core

The Light Core is comprised of the handle, light intensity controls, bulb housing and IR filters. The handle is used to articulate the light housing. The light intensity controls are in the handle and permit the intensity of the light to be increased and decreased. The intensity level is indicated via a series of LED indicators that are located on a fascia plate adjacent to the handle. Behind the fascia plate, concealed behind the lens, are the bulbs (the BRIGHTSTAR primary bulb and the secondary back up bulb). The bulb is located behind a series of IR glass filters.

The entire Light Core may be removed without the use of special tools to facilitate changing the bulbs.

(VII) Controls

Controls for the light are provided as a wall mount and handle mount. The Controls provide the ability to increase/decrease the light intensity and turn the task light on/off. The mains power indicator as well as the replace-lamp indicator is also located on the control panel.

The BRIGHTSTAR uses software to coordinate the wall mounted and light mounted controls. This is a feature designed for the convenience of the user and represents a low level of concern should the software malfunction.

Voluntary Standards

The BRIGHTSTAR will comply with the appropriate sections of the following documents:

- UL 2601-1 (1st Edition) Medical Electrical Equipment Regulatory Standard
- CSA C22, No. 601.1 Canadian Safety Standard
- IEC 601-1 (Second Edition) Medical Electrical Equipment – General Requirements for Safety
- IEC 601-1-4, (1st Edition) Programmable Electrical Medical Systems

Intended Use:

The BRIGHTSTAR Surgical Light is intended for use in surgical and non-surgical applications to provide illumination of the surgical field or the patient. It is capable of being used with a broad patient population as determined appropriate by the caregiver or institution.

Design and Construction:

The BRIGHTSTAR is primarily composed of aluminum and steel in the structural components. Tempered glass is used for the IR filters and Lexan® is used for the diffuser.

Statement of Substantial Equivalence

The subject device and predicate device(s) in this submission are substantially equivalent. The subject device has the same or similar materials, technology and performance characteristics as the predicate devices. The BRIGHTSTAR does not raise any new safety and effectiveness concerns.

Product Comparison

Manufacturer	Hill-Rom BRIGHTSTAR	AMSCO Quantum SQ240	Berchtold Chromophare 571
# of Bulbs	1	1	1
Back-up Bulb	Yes	Yes	Yes
Spare Bulb Storage	Yes	No	No
Color Temperature (^{0}K)	4,200^{0}K	4,400^{0}K	4,500^{0}K
Pattern Size (inches)	6-11	6.5-11	7.5-11.8
Focal Length	1 meter	1 meter	1 meter
Illumination-Ft Candles (Lux)	12,000 (130,000)	12,000 (129,170)	9,293 (100,000)
Cavity Penetration	90% +/-5	90% +/-5	90% +/-5
Shadow Control	30-35%	30-35%	30-35%
Controls:			
• Dimmer	5 increments Handle	3 Levels	50-100% Light
• Pattern Adjustment	360^0 Twist of Sterile Hand	Small & Large	Rotate Sterile Handle
• Depth of Field (ins)	20 minimum	26	19.68
Wall Plate Controls:			
• Dimmer	Yes	Yes	Yes
• On-Off/Standby	Yes	Yes	Yes
• Task Light On/Off	Yes	No	No
Sterile Handle Controls	Yes	No	No
Rotation	360^0	360^0	360^0

Product Comparison

	Hill-Rom BRIGHTSTAR	AMSCO Quantum SQ240	Berchtold Chromophare 571
Vertical Adjustment (ins)	Adjusted when Installed	Adjusted when Installed	Adjusted when Installed
Heat Filtering	IR Filter	IR Filter	IR Filter
Filter Material	IR Glass	IR Glass	IR Glass
Reflector Material	Vacuum Metalized A_L	Regular Reflector	Regular Reflector
Task Light	Yes, 20 Watt	No	20 Watt
Sterile Handle:			
• Sterile Cover	Yes	Yes	Yes
• Replacement Handle	No	Yes	Yes
'Zero' Drift Arm	Yes	Yes	Yes
Diameter (inches)	25 inches	24	22.4
Mounting Options	Ceiling	Ceiling Single or Double Plus Track	Ceiling Single or Double
Supply Voltage	120V 220/240V	120V 220/240V	110V 230/240V
Power (Watts)	180	220	150
Bulb:			
• Life	1000 Hrs	1,000 Hrs	1,000 Hrs
• Type	Quartz Halogen	Quartz Halogen	Quartz Halogen
• Voltage	24V DC	24V DC	24V DC

SUMMARY OF SIMILARITIES AND DIFFERENCES

The design and features offered by the Hill Rom Surgical Light are similar to the design and features of the predicate devices.

Similarities

Shadow Control

Each light is designed to have a single bulb, single reflector. Both the BRIGHTSTAR and the predicate devices will tolerate at least 30-35% of the light source being blocked without casting a significant shadow over the surgical site being lit.

Pattern Adjustment

The BRIGHTSTAR and predicate devices provide the ability to adjust the pattern size. The range of adjustment being approximately 6-12 inches. The light adjustment is achieved by adjusting the focal distance of the bulb to the reflector.

Color Correction

Bulb color temperature for both the BRIGHTSTAR and predicate devices is between 4,000-4,800^{O}K This color temperature has been demonstrated to maintain skin color and integrity, both on the surface and in open wounds.

Light Intensity Adjustment

Light intensity for the BRIGHTSTAR and the predicate devices is adjusted by increasing the driving voltage on the bulb(s) to achieve a corresponding increase/decrease in light output.

Articulation Positioning of the Light

The range of motion offered by the BRIGHTSTAR and the predicate devices is identical. The lamp head itself is connected to this arm indirectly via a connecting arm, which rotates radially through an arc of 180^{O}-210^{O} thus allowing the light to be adjusted to any working height. The light housing is attached to the radial arm by way of a yoke, which allows the head to rotate in a circular motion.

Light Output

Light output for the BRIGHTSTAR is 12,000 Ft. Candles. The predicate devices light output ranges from 9,293 to 12,000 Ft. Candles.

Light Positioning

The position of the BRIGHTSTAR can be positioned either by using the sterile handle or by using the grab handles located on the outer edge of the light housing which are outside of the sterile field. This is similar to the positioning options offered on the predicate devices.

Configuration

The BRIGHTSTAR is available in either a single or double light head set up. The lights all mount to a common point within the ceiling and have arms of different lengths that pivot about the same point. The predicate devices also offer similar configurations.

Differences

Software Controls

The BRIGHTSTAR uses software to coordinate the wall mounted and light mounted controls. The predicate devices do not utilize software. This is a feature designed for the convenience of the user and represents a low level of concern should the software malfunction.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 29 1998

Mr. William D. Jordan
Regulatory Specialist
Hill-Rom® Company, Incorporated
1069 State Route 46 East
Batesville, Indiana 47006-9167

Re: K981081
Trade Name: Bright Star
Regulatory Class: II
Product Code: FSY
Dated: March 20, 1998
Received: March 24, 1998

Dear Mr. Jordan:

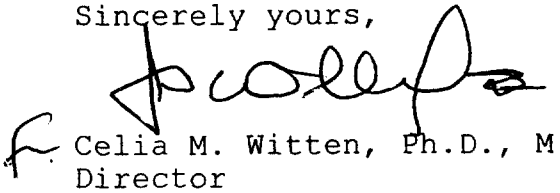
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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,



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

Indications for Use

510(k) Number: Unknown

Device Name: BRIGHTSTAR

Indications for Use:

The BRIGHTSTAR Surgical Light is intended for use in surgical and non-surgical applications to provide illumination of the surgical field or the patient. It is capable of being used with a broad patient population as determined appropriate by the caregiver or institution.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1/2/96)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K981081