SEP 1 9 2002

K022196

natus®

8 510(k) Summary of Safety and Effectiveness

This summary is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: _____

1. Submitter

Natus Medical Inc.
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San Carlos, CA 94070
Phone: 650) 802-0400
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Contact	Sheila Ramerman, Director RA/QA
Date Prepared:	July 3, 2002

2. Device Names

Classification name	Unit, Neonatal Phototherapy
Common names	Phototherapy Light, Bili Light
Trade name	Natus® Blue Light Phototherapy Unit

3. Predicate Device

Olympic Bili-Light, Model 33, K940996

4. Device Description

The Natus Blue Light Phototherapy Unit is a floor-standing, mobile phototherapy device that delivers a narrow band of high-intensity blue light via blue light emitting diodes (LEDs) to provide treatment for neonatal hyperbilirubinemia.

The device consists of a lightweight plastic light enclosure that can be tilted and adjusted both horizontally and vertically on a rollstand assembly. The light enclosure can be tilted to a maximum of approximately 40° up from horizontal (the resting position). The light enclosure height can be adjusted vertically along the rollstand post, as well as horizontally out from the rollstand post (proximity adjustment) to aid in positioning the device. A red target light can be briefly illuminated by the user, using a rocker switch on the front panel, to help position the device over the infant. The device can be used for infants in a bassinet, incubator, open bed, or radiant warmer.

There are two intensity settings, high and low. The user selects the desired setting using a rocker switch on the front panel of the device. The light output is optimized to provide an average intensity of 35 uW/cm^2/nm at the high setting and 15 uW/cm^2/nm at the low setting at 30 cm (12 inches) distance from the baby. A diffuser panel provides a more uniform illumination pattern from the multiple LED

light sources, and protects the user from viewing a single point source of light. The diffuser panel also protects the device from incidental debris or fluid exposure.

Blue LEDs emit light in the range of 400 – 550 nm (peak wavelength 450-475 nm). This range corresponds to the spectral absorption of light by bilirubin, and is thus considered to be the most effective for the degradation of bilirubin. Blue LEDs do not emit significant energy in the ultraviolet (UV) region of the spectrum, so there is no concern about UV exposure to the infant. In addition, blue LEDs do not emit significant energy in the infrared (IR) region of the spectrum, so there is no concern about IR exposure and excessive warming of the infant. As with all phototherapy devices, protective eye shades should be used to protect the infant's eyes from excessive light exposure.

LEDs have minimal light output degradation over their lifetime with proper use. Nevertheless, the user can adjust the output of the LEDs using two potentiometers located on the side of the light enclosure. Instructions for adjusting the output are included in the User Manual (see Appendix A). A drawing of the location of the location of the potentiometers is included in Appendix C. In normal operating conditions the device is expected to operate as specified approximately 10,000 hours at the low setting, and approximately 3,000 hours at the high setting. No pre-aging of the LEDs is required; the LEDs are 'burned in' at the factory.

The Natus Blue Light device is mains-power operated. The power cord plugs into a receptacle at the power inlet at the back of the light enclosure.

There are no single-use components or accessories for the Natus Blue Light Phototherapy device.

5. Intended Use

The Natus® Blue Light Phototherapy Unit is a floor-stand, mobile phototherapy light intended for the treatment of neonatal hyperbilirubinemia. The device can be used for infants in a bassinet, incubator, open bed, or radiant warmer. It emits a narrow band of blue light considered to be the most effective in degradation of bilirubin.

6. Comparison with Predicate Device

The Natus Blue Light Phototherapy Unit and the Olympic Bili-Lite Model 33 have the same intended use (treatment of hyperbilirubinemia), use the same operating principle (delivery of light to degrade bilirubin), and are similar in their hardware configuration. See the Comparison Table below for details.

Comparison Table

Natus® Blue Light vs. Olympic Bili-lite™ Model 33

Feature	Natus Blue Light	Olympic Bili-Lite (K940996)
Intended Use	For the treatment of neonatal hyperbilirubinemia	For the treatment of neonatal hyperbilirubinemia
Target population	Neonates	Neonates
Sites of use	Nursery, doctor's office, anywhere phototherapy is delivered	Nursery, doctor's office, anywhere phototherapy is delivered
Physical Design		
Type	Freestanding device	Freestanding device
Mounting hardware	Roll Stand, 5 legs w/casters, 2 locking	Roll Stand, 4 legs w/casters
Light attachment	Lights mounted in hood enclosure	Lights mounted in hood enclosure
Width, light enclosure	20.5 in (52 cm)	25 in (63.5 cm)
Depth, light enclosure	10.5 in (27cm)	19 in (48 cm)
Weight (light on stand)	< 35 lb. (< 16kg)	Approx. 80 lbs (36 kg)
Height	43–60 in, adjustable	43.5–60 in, adjustable
Light enclosure tilt	Standard 0° to ~ 40° from horizontal	Optional 0° to 60° from horizontal
Accessories	None	Tilt Attachment, Bili-timer
Performance Specifications		
Light source		
• Type	• Light Emitting Diodes (LED)	• Fluorescent
• Number	• Approx. 750 LEDs	• 8-20 W tubes
• Life	• 10,000 hr (low setting) 3,000 hr (high setting)	• 200 hours minimum 9000 hour maximum
• Color	• Blue	• Blue (standard configuration) • White (daylight, optional) • High-intensity blue (optional)
Wavelength	400-550 nm Peak @ 450–475 nm	400–520 nm Peak: not stated
Intensity	Low: 15 ± 2 $\mu W/cm^2/nm$ High: 35 ± 3.5 $\mu W/cm^2/nm$	9 $\mu W/cm^2/nm$ (White bulbs) 20 $\mu W/cm^2/nm$ (Blue) 40 $\mu W/cm^2/nm$ (hi intensity)
Light intensity adjustment	High/Low switch adjusts between two levels of intensity	Adjust light enclosure height (distance from baby)
Operating Voltage	85–264VAC	106-127 VAC, 60 Hz or 194-233VAC, 50 Hz
Overload protection (fuses)	2A @ 120V	2A @ 120V
Current Leakage	< 100 uA	@120 VAC: < 100 uA @220VAC: <150 uA
Fan	24 VDC Fan	Not applicable (no fan)

Feature	Natus Blue Light	Olympic Bili-Lite (K940996)
Acoustic Noise	< 35 dB	Not available
Operating temperature	50 - 86º F (10 - 30º C)	60 - 99º F (15.5 – 37ºC)
Storage temperature	23 - 122º F (–5 to +50º C)	-30 - +150º F (-34 to +65.5ºC)
Operating humidity	10 to 90% non-condensing	0% - 95% RH
Storage humidity	0 to 90% non-condensing	0% - 95% RH
Standards and Safety		
Electrical safety	EN 60601-1 and 1-1-2 UL 2601-1 CSA/CAN C22.2 601.1 EN 60601-2-50	UL 544 CSA/NRTL
Mechanical safety	Plastic diffuser minimizes accidental viewing of single point light source Diffuser protects baby and lights from incidental debris or fluids	Transparent plastic shield under bulbs prevents injury from broken glass
Thermal safety	Fan to cool circuitry, minimize device heating LEDs give off little heat, by design	Height adjustment prevents patient overheating
Radiation safety	LED light source produces minimal ultraviolet light	Transparent plastic shield under bulbs filters out UV radiation
Human Factors		
Controls and Indicators	• On/Off power switch • High/low intensity switch • Positioning light	• On/Off power switch
Compatibility with environment or other devices	Can be used outside a bassinet or incubator, under a radiant warmer Tilt adjustments standard	Can be used outside a bassinet or incubator Requires tilt attachment for use under radiant warmer

7. Summary of Nonclinical Testing

This submission includes the results of testing prototype devices to specifications, spectral characterization of the blue LED light source, and an analysis of the potential optical radiation hazard of the blue LED light source. The results were as expected and no new issues of safety or effectiveness were raised as a result of the nonclinical testing.

Conclusions

Based on the data and information presented in this submission, the Natus® Blue Light Phototherapy Unit is substantially equivalent to the currently legally marketed Olympic Bili-lite™ Model 33, manufactured and distributed by Olympic Medical.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 19 2002

Ms. Sheila Ramerman
Director, RA/QA
Natus Medical, Incorporated
1501 Industrial Road
San Carlos, California 94070

Re: K022196
Trade/Device Name: Natus® Blue Light Phototherapy Unit
Regulation Number: 880.5700
Regulation Name: Neonatal Phototherapy Unit
Regulatory Class: II
Product Code: LBI
Dated: July 3, 2002
Received: July 5, 2002

Dear Ms. Ramerman:

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.

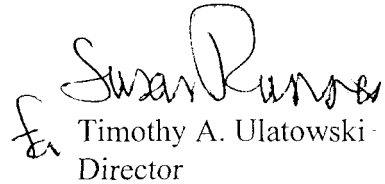
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. 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). 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,



for Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

7 Indications For Use Statement

510(k) Number (if known): K022196

Device Name: Natus® Blue Light Phototherapy Unit

Indications for Use:

The Natus® Blue Light Phototherapy Unit is a floor-stand, mobile, phototherapy light intended for the treatment of neonatal hyperbilirubinemia. The device can be used for infants in a bassinet, incubator, open bed, or radiant warmer.
It emits a narrow band of blue light considered to be the most effective in the degradation of bilirubin.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Optional Format 1-2-96)

Patricia Cucerte
(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number K022196