DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 7 2005

Ms. Luanne Ng
Regulatory/Clinical Affairs Manager
Natus Medical, Incorporated
1501 Industrial Road
San Carlos, California 94070

Re: K051869
Trade/Device Name: NEOBLUE COZY LED PHOTOTHERAPY SYSTEM
Regulation Number: 21 CFR 880.5700
Regulation Name: Neonatal phototherapy unit
Regulatory Class: II
Product Code: LBI
Dated: October 21, 2005
Received: October 24, 2005

Dear Ms. Ng:

This letter corrects our substantially equivalent letter of October 7, 2005.

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 (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 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 continue 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 (240) 276-0115. 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 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,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K051869

Device Name: neoBLUE cozy™ LED Phototherapy System

INDICATIONS FOR USE: The neoBLUE cozy phototherapy light is intended for the treatment for neonatal hyperbilirubinemia. It is designed to provide phototherapy treatment from underneath the baby. The neoBLUE cozy system must be used within a patient enclosure, such as a bassinet, an open crib, a warming table or an incubator. The neoBLUE cozy system can be used in a clinical setting or in the home.

Prescription Use X AND/OR Over-The-Counter Use
(Part 21 CFR 801 Supbart B) (21 CFR 801 Subpart C)

(PLEASE DONOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K051869

8 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Submitter

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Contact: Luanne Ng
Regulatory/Clinical Affairs Manager

Date Prepared: July 7, 2005

Device Names

Classification name: Unit, Neonatal Phototherapy

Common name: Phototherapy Light

Trade Name: Natus® neoBLUE cozy systemPhototherapy Unit

Predicate Devices

Medela Bilibed, K962612
Natus Blue Light Phototherapy Unit, K022196

Device Description

The neoBLUE cozy system is a portable phototherapy light that delivers a narrow band of high-intensity blue light via blue light emitting diodes (LEDs) to provide treatment for neonatal hyperbilirubinemia. The neoBLUE cozy system is designed to provide phototherapy treatment from underneath the baby. The neoBLUE cozy system must be used within a patient enclosure, such as a bassinett, an open crib, a warming table or an incubator.

Blue LEDs emit light in the range of 400 – 550 nm (peak wavelength 450-470 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. As with all phototherapy lights, protective eyeshades must 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 biomedical engineer can adjust the output of the LEDs using the

potentiometer located behind the filter cover at the flat end of the light enclosure. The system is expected to operate at intensities above 30 uW/cm2/nm for approximately 3,000 hours.

The neoBLUE cozy system consists of five components: the neoBLUE cozy light source (light), the mattress, the disposable mattress cover, the bumper accessory, and the power supply.

Intended Use

The neoBLUE cozy system is a portable phototherapy light that delivers a narrow band of high-intensity blue light via blue light emitting diodes (LEDs) to provide treatment for neonatal hyperbilirubinemia. The neoBLUE cozy system is designed to provide phototherapy treatment from underneath the baby. The neoBLUE cozy system must be used within a patient enclosure, such as a bassinett, an open crib, a warming table or an incubator. The neoBLUE cozy system can be used in a clinical setting or in the home.

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The neoBLUE cozy system can be used in conjunction with an overhead phototherapy light for more patient surface area coverage. A simple blanket may be placed over the patient during phototherapy treatment with the neoBLUE cozy system to protect the surroundings from stray blue light.

Comparison with Predicate Device

The neoBLUE cozy system, the Medela BiliBed and the Natus Blue Light Phototherapy Unit have the same intended use of treatment of neonatal hyperbilirubinemia and use the same operating principle of delivery of light to degrade bilirubin. See the Comparison Table below for details.

Feature	**Natus neoBLUE cozy LED Phototherapy System**	**Medela BiliBed (K962612)**	**Natus Blue Light Phototherapy Unit (K022196)**
Intended Use	For the treatment of neonatal hyperbilirubinemia	For the treatment of neonatal hyperbilirubinemia	For the treatment of neonatal hyperbilirubinemia
Treatment Method	Underbaby phototherapy	Underbaby phototherapy	Overhead phototherapy
Targeted Population	Neonates	Neonates	Neonates
Sites of Use	Clinical setting, home-use	Clinical setting, home-use	Clinical setting

Feature	Natus neoBLUE cozy LED Phototherapy System	Medela BiliBed (K962612)	Natus Blue Light Phototherapy Unit (K022196)
Specifications			
Type of Device	Free standing device	Free standing device	Free standing device
Type of Light	Blue light (LED)	Blue light fluorescent	Blue light (LED)
Intensity	30-35 $\mu W/cm^2/nm$	Approx. 40-60 $\mu W/cm^2/nm$ or more	30 – 35 $\mu W/cm^2/nm$
Height	≤6.4 cm (2.5 in) patient surface, ≤12.7 cm (5.0 in) rest of device	13.0 cm (5.1 in), including baby support	Not Applicable
Width and Length	30.5 cm (12.0 in) width x 64.8 cm (25.5 in) length	32.6 cm (12.8 in) width x 63 cm (24.8 in) length	Not Applicable
Weight	<4.3 kg (9.5 lbs)	5 kg (11 lbs)	Not Applicable
Treatment area	Minimum 613 cm^2 (95 in^2)	Not Published	1250 cm^2 (200 in^2)
Materials			
Device	Polycarbonate cover & polyurethane base	Aluminum frame, plastic base	Not Applicable
Mattress	Polyurethane cover with polyolefin bubble cushioning	Polyurethane plastic	Not Applicable
Mattress Cover	Nonwoven spunlaced polyester	Bilicombi – 100% cotton or 100% nonwoven spunlaced fabric	Not Applicable
Patient side cushioning/Jacket	Foam bumper encased by 100% cotton fabric	Bilicombi – 100% cotton or 100% nonwoven spunlaced fabric	Not Applicable
Miscellaneous			
Shape	Oval with flat end at foot area	Rectangle	Not Applicable
Portable	Yes with carrying case	Yes with carrying case	Not Applicable
Patient side cushioning/Jacket	Foam bumper encased by 100% cotton fabric	Bilicombi – 100% cotton or 100% nonwoven spunlaced fabric	Not Applicable

Feature	Natus neoBLUE cozy LED Phototherapy System	Medela BiliBed (K962612)	Natus Blue Light Phototherapy Unit (K022196)
Standards and Safety			
Electrical Safety	EN 60606-1 UL 2601-1 CSA C22.2 601.1 EN 60601-2-50	UL 2601-1 IEC 529	EN 60606-1 UL 2601-1 CSA C22.2 601.1 EN 60601-2-50
Mechanical Safety	Disposable cover acts as a diffuser to minimize accidental viewing of single point light source	Not Applicable	Plastic diffuser minimizes accidental viewing of single point light source
Thermal Safety	Fan to cool circuitry, minimize device heating. Thermal protection circuit – turns off LEDs if device gets too warm.	Fan to cool	Fan to cool circuitry, minimize device heating
Radiation Safety	LED light source emits no significant ultraviolet light	Fluorescent light sources may produce minimal ultraviolet light	LED light source emits no significant ultraviolet light
Ingress of Liquids	IPX4	IPX1	Not Applicable
Human Factors			
Controls and Indicators	On/Off switch. Overheat indicator light	On/Off switch	On/Off switch. High/Low intensity switch. Positioning light.
Compatibility with environment or other devices	Used inside bassinet, open crib, warmer table, incubator	Used inside bassinet and/or under radiant warmer	Used in conjuntion with a bassinet, open crib, warmer table, incubator

Summary of Nonclinical Testing

This submission includes the results of testing of prototype devices to specifications. The results were as expected and no new issues of safety and effectiveness were raised as a result of the nonclinical testing.

Conclusion

Based on the data and the information presented in this submission, the neoBLUE cozy LED Phototherapy System is substaintially equivalent to the currently marketed Medela BiliBed and the Natus Blue Light Phototherapy Unit (for the blue LED light only).