MAY 1 3 2011

5 – Summary of Safety and Effectiveness

As required by 21 CFR, part 807.92

a)	1.	Submitted By:	Natus Medical Incorporated Olympic Medical Division 5900 First Avenue South Seattle, WA 98108
		Contact:	Julie Freed, Ph.D. Senior Regulatory Affairs Specialist P (206) 268-5170 F (206) 268-5104
		Date Summary Prepared:	May 10, 2011
	2.	Proprietary Name:	neoBLUE® blanket LED Phototherapy System
		Common/Usual Name:	Neonatal phototherapy unit
		Classification:	Class 2, Product Code LBI, 21CFR Part 880.5700
	3.	Predicate Device(s):	Olympic Bili-Lite Pad (K901987) Natus neoBLUE cozy LED Phototherapy System (K051869) BiliSoft Phototherapy System (K053568)
	4.	Device Description:	A neonatal phototherapy system composed of a mobile light box coupled to a fiberoptic blanket. The re-usable fiberoptic blanket is covered with a mattress and a disposable cover.
	5.	Intended Use:	The neoBLUE blanket LED Phototherapy System is intended for the treatment of neonatal hyperbilirubinemia. It can be used in the clinical setting or in the home.
	6.	Technological Characteristics:	The mobile light box is composed of a single "Large Format" LED (light-emitting diode) with a peak wavelength of 460 nm. A custom optic directs light from the LED into the fiberoptic blanket. The power supply for the light box is exterior to the light box and is connected by a cable. The fiberoptic blanket is composed of high performance plastic optical fibers enclosed in a vinyl material. A polyurethane mattress is placed on top of the fiberoptic blanket. A disposable cover made of non-woven polypropylene is placed on top of the mattress. The fiberoptic blanket generates sufficient light output to provide intensive phototherapy (>30μW/cm^2/nm). This light output is achieved for both the large blanket and the small blanket. Accessories sold with the neoBLUE blanket include the mattress, the disposable covers, and a pole mounting clamp.

b)	1.	Non-clinical Testing Performed:	Biocompatibility tests performed per ISO 10993 for patient contacting materials (mattress and disposable cover). Bench tests performed to measure spectral output, light irradiance and effective surface treatment area. Electrical safety tests performed per IEC 60601-1 (2^{nd} edition) and 60601-1-2 (EMI/EMC). Phototherapy safety and performance tests performed per IEC 60601-2-50 (1^{st} edition).
	2.	Clinical Tests Performed:	Not Applicable
	3.	Testing Summary:	The mattress and disposable cover passed Cytotoxicity, Sensitization and Skin Irritation tests. The neoBLUE blanket LED Phototherapy System has been tested to ensure compliance with all appropriate sections of IEC 60601-1, IEC 60601-1-2 and IEC 60601-2-50. Using the method described in IEC 60601-2-50, the effective surface treatment area was measured to be 504 cm^2 for the large blanket and 296 cm^2 for the small blanket. In conclusion, data from the non-clinical tests and a comparison of the technology, device specifications, intended use, target population and other device features demonstrates that the neoBLUE blanket LED Phototherapy System is substantially equivalent to the predicate devices listed in Section 3.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MAY 13 2011

Dr. Julie Freed
Senior Regulatory Affairs Specialist
Natus Medical Incorporated
Olympic Medical Division
5900 First Avenue South
Seattle, Washington 98108

Re: K103589
Trade/Device Name: NeoBLUE Blanket LED Phototherapy System
Regulation Number: 21 CFR 880.5700
Regulation Name: Neonatal Phototherapy Unit
Regulatory Class: LBI
Product Code: II
Dated: May 4, 2011
Received: May 5, 2011

Dear Dr. Freed:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/ default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
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

510(k) Number (if known): K103589

Device Name: neoBLUE blanket LED Phototherapy System

Indications for Use:

The neoBLUE blanket LED Phototherapy System is intended for the treatment of neonatal hyperbilirubinemia. It can be used in the clinical setting or in the home.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

5/11/11

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

510(k) Number: K103589