DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

May 27, 2016

Natus Medical Incorporated
Ms. Judy Buckham
Regulatory Affairs Specialist
5900 First Avenue South
Seattle, Washington 98108

Re: K160305
Trade/Device Name: neoBLUE® LED Phototherapy System
Regulation Number: 21 CFR 880.5700
Regulation Name: Neonatal Phototherapy Unit
Regulatory Class: Class II
Product Code: LBI,
Dated: April 14, 2016
Received: April 18, 2016

Dear Ms. Buckham:

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 contact the Division of Industry and Consumer Education 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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,

Tina Kiang
-S

for Erin I. Keith, M.S.
Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K160305

Device Name
neoBLUE® LED Phototherapy System

Indications for Use *(Describe)*

Indications for Use: The neoBLUE® LED Phototherapy System is indicated for the treatment of hyperbilirubinemia for neonates and infants in a hospital environment, and administered by trained, professional medical staff, on the order of a licensed medical practitioner. The light can be used with a bassinet, incubator, open bed, or radiant warmer.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K160305 510(K) SUMMARY

Manufacturer's Name:	Natus Medical Incorporated 5900 First Avenue South Seattle, WA 98108
Corresponding Official:	Judy Buckham Regulatory Affairs Specialist
Telephone Number:	206 268 5187
Fax Number:	206 268 5104
Preparation Date:	April 14, 2016
Trade Name:	neoBLUE® LED Phototherapy System
Common or Usual Name:	Neonatal Phototherapy Unit
Classification Name and Number:	Unit, Neonatal Phototherapy 21 CFR 880.5700 Product Code: LBI
Predicate Device:	K022196 Natus Blue Light Phototherapy Unit

Device Description

The neoBLUE® Phototherapy System consists of two products – the neoBLUE LED Phototherapy light source (light) and the neoBLUE LED Phototherapy roll stand.

The neoBLUE LED Phototherapy System is a floor-standing, mobile 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 light can be used independently of the roll stand, and can be placed directly on an incubator with a flattopped surface.

Intended Use

The neoBLUE LED Phototherapy System is indicated for the treatment of hyperbilirubinemia for neonates and infants in a hospital environment, and administered by trained, professional medical staff, on the order of a licensed medical practitioner. The light can be used with a bassinet, incubator, open bed, or radiant warmer.

The indications for use of the predicate (K022196) reference the phototherapy system as emitting "blue light." The indications for use for the subject device (neoBLUE LED Phototherapy System) do not include this statement because the system emits blue and yellow light. Removal of this sentence does not raise new questions of safety or effectiveness.

Technological Characteristics
The neoBLUE light has intensity settings, high and low, which are factory calibrated to provide intensity of 35 $\mu W/cm^2/nm$ at the high setting and 15 $\mu W/cm^2/nm$ at the low setting at a distance of 12 inches (30.5 cm) from the light enclosure to the baby. The light output can also be adjusted to accommodate different distances.

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, reducing the potential risk of skin damage. In addition, blue LEDs do not emit significant energy in the infrared (IR) region of the spectrum, minimizing concern about excessive warming of the infant.

The blue LEDs in the device produce the same therapeutic output as in the predicate. Yellow LEDs were intermixed with the blue LEDs in the new device so that the light output visually appears less blue in color, the light source was separated from the roll stand for independent use, and a timer was added to record the cumulative number of working hours for the LED lights.

Clinical Tests
N/A

Nonclinical Tests
The neoBLUE LED Phototherapy System passed all testing and complies with the following referenced standards:

- IEC 60601-2-50:2009-03 Edition 2; Medical Electrical Equipment – Part 2-50: Particular Requirements for the Basic Safety and Essential Performance of Infant Phototherapy Equipment
- IEC 60601-1:2005/(R)2012 and C1:2009/(R)2012; Medical Electrical Equipment –Part 1: General Requirements for Basic Safety
- IEC 60601-1-2: 2007/(R)2012; Medical Electrical Equipment Part 1-2: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Compatibility – Requirements and Tests
- IEC 60601-1-6:2013-10 Edition 3.1; Medical Electrical Equipment – Part 1-6: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Usability

In addition to compliance with the relevant standards, design verification and validation testing was performed to ensure that the neoBLUE LED Phototherapy System meets its performance specifications and demonstrates equivalence to the predicate device (K022196).

Conclusions

The performance verification/validation testing data and risk analysis documentation provided in this 510(k) support the conclusion that the neoBLUE LED Phototherapy system performs as intended and is substantially equivalent to the predicate device.

The neoBLUE LED Phototherapy System is substantially equivalent to the Natus Blue Light Phototherapy Unit cleared under K022196.