DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

December 12, 2016

Natus Medical Incorporated
Therese Leggiere
Director, Quality and Regulatory Affairs
5900 First Avenue South
Seattle, Washington 98108

Re: K160745
Trade/Device Name: neoBLUE Compact LED Phototherapy System
Regulation Number: 21 CFR 880.5700
Regulation Name: Neonatal Phototherapy Unit
Regulatory Class: II
Product Code: LBI
Dated: November 7, 2016
Received: November 8, 2016

Dear Therese Leggiere:

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, Ph.D.
Acting 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)*
K160745

Device Name
neoBLUE compact LED Phototherapy System

Indications for Use *(Describe)*
The neoBLUE compact LED Phototherapy System is intended for the treatment of neonatal hyperbilirubinemia. The light can be used for infants in 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.

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K160745/S001 510(K) SUMMARY

Manufacturer's Name:	Natus Medical Incorporated 5900 First Avenue South Seattle, WA 98108
Corresponding Official:	Therese Leggiere Director, Quality and Regulatory Affairs
Telephone Number:	206-268-5187
E-mail:	therese.leggiere@natus.com
Preparation Date:	December 8, 2016
Trade Name:	neoBLUE Compact LED Phototherapy System
Common or Usual Name:	Neonatal Phototherapy Unit
Classification Name and Number:	Neonatal Phototherapy Unit 21 CFR 880.5700 Product Code: LBI
Primary Predicate Device:	Medix MediLEDmini (K103735)
Secondary Predicate Device:	Medix MediLED (K083179)

Device Description

The neoBLUE compact LED Phototherapy System utilizes 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 compact LED Phototherapy System light consists of a lightweight plastic light enclosure which can be used independently by placing directly on top of an incubator, or with the arm, or with the arm and roll stand together. The arm can be attached to the pole mount accessory on most incubators and radiant warmers. The arm, when attached to the roll stand, can be used for infants in a bassinet, incubator, open bed, or radiant warmer.

The neoBLUE compact LED Phototherapy System light is equipped with a treatment timer to track the total number of treatment hours per patient, a device timer to track the total number of operating hours for the blue LEDs, and an exam light.

Intended Use

The neoBLUE compact LED Phototherapy System is intended for the treatment of neonatal hyperbilirubinemia. The light can be used for infants in a bassinet, incubator, open bed, or radiant warmer.

The predicate device, K103735, indications for use statement is identical to the subject device, K160745, except the predicate indication statement contains a statement of efficacy of blue light for the treatment of hyperbilirubinemia. This is not appropriate for an indication for use statement in a 510(k) application. Therefore, there are no substantive differences in the indication for use statements between the subject and predicate devices.

Substantial Equivalence Discussion

Device Characteristics	neoBLUE compact LED Phototherapy System K160745	Medix MediLEDmini K103735	Medix MediLED K083179
Intended Use	For the treatment of neonatal hyperbilirubinemia	same	same
Treatment Method	Overhead phototherapy	same	same
User	Healthcare professionals in a clinical setting	same	same
Sites of Use	The light can be used for infants in a bassinet, incubator, open bed or radiant warmer	same	same
Patient Population	Neonates	same	same
Technology			
Light Source	Blue and white Light Emitting Diodes (LEDs)	Blue Light Emitting Diodes (LEDs)	same
Wavelength	Peak @ 450 to 470 nm	Peak @ 440 to 460 nm	Peak @ 450 to 470 nm
Intensity	10 – 55 $\mu W/cm^2/nm$ @ 35 cm	>20 to >50 $\mu W/cm^2/nm$ @40 cm	40 $\mu W/cm^2/nm$ @ 40 cm 49 $\mu W/cm^2/nm$ @ 30 cm
Intensity Settings	2 settings (high, low)	3 settings (high, medium, low)	1 setting
Effective Treatment Area	700 cm^2 @ 35 cm height	660 cm^2 @ 40 cm height	800 cm^2 @ 40 cm height
Exam Light	White Light Emitting Diodes (LEDs)	none	same
Operating	100 to 240 VAC	same	same

Voltage			
Operating Frequency	50 to 60 Hz	same	same
Controls	On/Off switch, exam light switch	On/Off switch	On/Off switch for treatment (blue) and viewing (white) LEDs
	Two levels of intensity	Three levels of intensity	One level of intensity
	Treatment timer display and reset button	Treatment counter that can be reset	same
Configurations			
Light enclosure used alone	Light can be used alone on top of an incubator	Same	Light is not separable from the integrated arm and roll base
Light enclosure used attached to arm	Light can be attached to an optional arm for use with incubator and//or radiant warmer	Same	Similar – Light is attached to the arm for use with incubator and/or radiant warmer. The light/arm configuration is integrated with the roll base
Light enclosure used attached to arm and roll stand	Light is attached to the arm and the arm attached to a roll stand	Similar – Light is attached to the arm and the arm attached to a radiant warmer	Similar – Light is attached to the arm and the arm attached to the roll base. The light, arm and base are an integrated unit and not separable.
Light positioning	Light can be positioned over the infant in a bassinet, incubator, open bed or radiant warmer	Similar – Light can be positioned over the infant in an incubator and/or radiant warmer	Same
Safety Standards			
Mechanical Safety	No moving parts in contact with the subject	same	same
Electrical Safety	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-50	same	same
Thermal Safety	Fan to cool circuitry Thermal protection circuit	same	same
Radiation Safety	LED light source produces minimal UV and IR light	same	same

Discussion of Differences

Blue and White LEDs

Both predicates and the neoBLUE compact LED Phototherapy System use the same fundamental technology; blue light LED phototherapy for neonates. 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. The secondary predicate, K083179 and the neoBLUE compact both contain white LEDs for use as an exam light.

Blue and white LEDs do not emit significant energy in the ultraviolet (UV) region of the spectrum, so there is no UV exposure to the infant; nor do they emit significant energy in the infrared (IR) region of the spectrum, minimizing concern about excessive warming of the infant

All three devices utilize LEDs as the light source. The MediLEDmini uses only blue LEDs during phototherapy treatment, whereas the MediLED and the neoBLUE compact LED Phototherapy System both use blue mixed with white LEDs. The design of the neoBLUE compact LED Phototherapy System incorporates the white LEDs to soften the visual impact of blue light, and for use as an optional exam light before or after phototherapy. As white LEDs also emit blue light, all blue light intensity is included in the total blue light intensity measurement. Therefore, the difference in the LEDs does not raise any new questions of safety or effectiveness.

Intensity Settings

The neoBLUE compact LED Phototherapy System compact has two intensity settings, high and low. The predicate devices have one or three settings (high, medium and low). The difference in the intensity settings (1 versus 2 versus 3) does not raise any new questions of safety or effectiveness.

Treatment Area

The treatment area for the neoBLUE compact LED Phototherapy System is between the range of the treatment area of the predicates, slightly larger than the MediLEDmini and slightly smaller than the MediLED: 660 cm^2 @ 40 cm height for the MediLEDmini; 700 cm^2 @ 35 cm height for the neoBLUE compact LED Phototherapy System; and 800 cm^2 @ 40 cm height for the MediLED. This does not raise any new questions of safety or effectiveness.

The differences between the predicate devices, K103735 and K083179, do not raise any new questions of safety or effectiveness.

Performance Testing

According to the device features, the testing for the following standards were considered required for the device:

- IEC 60601-1:2005/®2012 and A1:2012 Medical Electrical Equipment – Part 1 General Requirements for Basic Safety and Essential Performance
- IEC 60601-1-2: Edition 4.0 2014-02; Medical Electrical Equipment – Part 1-2: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Disturbances – Requirements and Tests
- IEC 60601-2-50:2009; Medical Electrical Equipment – Part 2-50: Particular Requirements for the Basic Safety and Essential Performance of Infant Phototherapy Equipment

In addition to the compliance of voluntary standards, the following performance testing was necessary to make a substantially equivalent decision:

- Software Verification

- Design Verification and Validation
    - Device power
    - Electrical safety
    - Indicators
    - LED performance
    - Intensity levels
    - Intensity range
    - Effective treatment area
    - Usability
- Hazard Analysis
- Human Factors Validation Testing

The compliance to applicable standards as above mentioned indicates that the new device in this submission used the same standards as that of predicate device. Therefore, the compliance with relevant standards in addition to the software validation, design verification and validation, hazard analysis and human factors validation is adequate for the determination of substantial equivalence.

Clinical Tests

Not Applicable

Conclusions

The neoBLUE compact LED Phototherapy System has the same intended use and similar technological characteristics as the cleared devices. Moreover, verification and validation tests contained in this submission demonstrate that the difference in the submitted models do not raise new questions of safety and effectiveness as that of cleared device.

In the other words, those engineering differences do not: (1) affect the intended use or (2) alter the fundamental scientific technology of the device. Therefore, we conclude that the neoBLUE compact LED Phototherapy System is substantially equivalent to the Medix MediLEDmini (K103735) and Medix MediLED (K083179).