December 13, 2018

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

Re: K182178
Trade/Device Name: neoBLUE® blanket LED Phototherapy System
  Regulation Number: 21 CFR 880.5700
  Regulation Name: Neonatal Phototherapy Unit
  Regulatory Class: Class II
  Product Code: LBI
  Dated: November 12, 2018
  Received: November 13, 2018

Dear Judy 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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
medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Sapana Patel -S

For 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
Indications for Use

The neoBLUE blanket LED Phototherapy System is indicated for the treatment of unconjugated hyperbilirubinemia in a hospital environment, and administered by trained professional medical staff, on the order of a physician, or in the home environment administered by a trained caregiver. The neoBlue blanket device provides intensive phototherapy underneath the patient and can be used with a bassinet, open bed, radiant warmer, incubator, or while holding the patient.

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.

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510(k) Summary K182178

Manufacturer’s Name: Natus Medical Incorporated
5900 First Avenue South
Seattle, WA 98108

Corresponding Official: Judy Buckham
Senior Regulatory Affairs Specialist

Telephone Number: 206 268 5187
Fax Number: 206 268 5104

Summary Date: 12 December 2018

Trade Name: neoBLUE® blanket LED Phototherapy System

Common or Usual Name: Neonatal Phototherapy Unit

Regulation Name: Unit, Neonatal Phototherapy

Regulation Number: 21 CFR 880.5700

Product Code: LBI

Predicate Device: K103589 neoBLUE blanket LED Phototherapy System

Device Description:

The neoBLUE blanket LED Phototherapy System is a portable phototherapy system that consists of five components: the neoBLUE blanket phototherapy light box, fiber optic blanket with attached cable, blanket mattress, disposable mattress covers, and power supply. The neoBLUE blanket LED Phototherapy System delivers a narrow band of high-intensity blue light via a blue light emitting diode (LED), in order to provide treatment for neonatal hyperbilirubinemia.

The neoBLUE blanket LED Phototherapy System is for the treatment of unconjugated hyperbilirubinemia in premature babies and neonates. It is intended for use with patients up to 3 months of age, weighing less than 22 lb (10 kg).
The portable neoBLUE blanket light box contains a blue LED which emits light in the range of 400 – 550 nm (peak wavelength 450-475 nm). This blue light is directed through an optical fiber cable to the fiber optic blanket pad. The fiber optic blanket pad is composed of high performance optical fibers enclosed in a vinyl material. A polyurethane mattress is placed on top of the fiber optic blanket, and a disposable polypropylene cover is placed around the blanket pad and mattress. The fiber optic blanket generates sufficient light output to provide intensive phototherapy which is defined as ≥30µW/cm²/nm.

The spectrum range of the blue LED light corresponds to the spectral absorption of light by bilirubin, and is thus considered to be the most effective for the degradation of bilirubin.

The neoBLUE blanket device can be directly connected to nominal voltages readily available throughout the world as the external power supply provided with this device is rated for use with 100-240 Volts at either 50 or 60 Hz. This external power supply provides 12 VDC to the light box, and plugs in to a receptacle at the rear of the light box.

**Environment**

Operating temperature/Humidity:
- Light box: 41° to 86° F (5 to 30°C)/10% to 90%, non-condensing
- Blanket: 41° to 100° F (5 to 38°C) / 10% to 90% non-condensing

Storage temperature/humidity: 32° to 122° F (0 to 50°C) / 10% to 90%, non-condensing

Altitude / Atmospheric pressure: 700 hPa to 1060 hPa

**Indications for Use:**

The neoBLUE blanket LED Phototherapy System is indicated for the treatment of unconjugated hyperbilirubinemia in a hospital environment, and administered by trained professional medical staff, on the order of a physician, or in the home environment administered by a trained caregiver. The neoBLUE blanket device provides intensive phototherapy underneath the patient and can be used with a bassinet, open bed, radiant warmer, incubator, or while holding the patient.

**Technological Characteristics:**
### Predicate Comparison Table

<table>
<thead>
<tr>
<th>Device Attribute</th>
<th>neoBLUE® blanket LED Phototherapy System K103589</th>
<th>neoBLUE® blanket LED Phototherapy System Updated Device</th>
<th>Discussion of Differences</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Indications for Use</strong></td>
<td>For the treatment of neonatal hyperbilirubinemia. It can be used in the clinical setting or in the home.</td>
<td>The neoBLUE blanket LED Phototherapy System is indicated for the treatment of unconjugated hyperbilirubinemia in a hospital environment, and administered by trained professional medical staff, on the order of a physician, or in the home environment administered by a trained caregiver. The neoBLUE blanket device provides intensive phototherapy underneath the patient and can be used with a bassinet, open bed, radiant warmer, incubator, or while holding the patient.</td>
<td>The differences in the Indications for Use statement do not raise different questions about the safety or effectiveness of the updated device. The statement was revised from that of the predicate to be more descriptive of the use environment. Additionally, the statement was updated to indicate the use from “treatment of hyperbilirubinemia” to the more specific “treatment of unconjugated hyperbilirubinemia.”</td>
</tr>
<tr>
<td><strong>Intended Use</strong></td>
<td>For the treatment of neonatal hyperbilirubinemia. It can be used in the clinical setting or in the home.</td>
<td>The neoBLUE blanket LED Phototherapy System is for the treatment of unconjugated hyperbilirubinemia in premature babies and neonates. It is intended for use with patients up to 3 months of age, weighing less than 22 lb (10 kg).</td>
<td>The differences in the Intended Use statement do not raise questions about the safety or effectiveness of the updated device. This change provides more specific information related to the patient population.</td>
</tr>
<tr>
<td><strong>Contraindications</strong></td>
<td>none</td>
<td>• Congenital porphyria or a family history of porphyria • Concomitant use of drugs or agents that are photosensitizers</td>
<td>Two contraindications published in AAP Guidelines were added to the User Manual. Neither of these raise questions about the safety or effectiveness of the updated device.</td>
</tr>
<tr>
<td><strong>Sites of Use</strong></td>
<td>Clinical setting or home use</td>
<td>Clinical setting or home use</td>
<td>Same</td>
</tr>
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<td>Device Attribute</td>
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<tr>
<td>------------------</td>
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<td>-------------------------------------------------------</td>
<td>---------------------------</td>
</tr>
</tbody>
</table>
| Device Components | • Light Box  
• Fiber optic blanket (2 sizes)  
• Blanket mattress (2 sizes)  
• Disposable mattress cover  
• Power cord | • Light Box  
• Fiber optic blanket (2 sizes)  
• Blanket mattress (2 sizes)  
• Disposable mattress cover  
• Power cord | Same |
| Light source | Single “Large Format” Blue LED coupled to fiber optic blanket | Single “Large Format” Blue LED coupled to fiber optic blanket | Same |
| Expected LED life | >20,000 hours | >20,000 hours | Same |
| Treatment Wavelength | Blue wavelength 400-550 nm  
Peak @ 450-475 nm | Blue wavelength 400-550 nm  
Peak @ 450-475 nm | Same |
| neoBLUE blanket LED Phototherapy System Light Intensity | >30 µW/cm²/nm for both blanket sizes. Factory set at 30-35 µW/cm²/nm | ≥30 µW/cm²/nm for both blanket sizes. Factory set at 35 ± 5 µW/cm²/nm | There were no design changes made to the intensity of the system, just a clarification to the specification. |
| Light Box Materials | Polycarbonate light box enclosure and aluminum handle | Polycarbonate light box enclosure and aluminum handle | Same |
| Fiber optic Blanket Dimensions | Large: 9.5 x 14.5 in (24.1 x 36.8 cm)  
Small: 6.75 x 12.75 in (17.1 x 32.4 cm) | Large: 9.5 x 14.5 in (24.1 x 36.8 cm)  
Small: 6.75 x 12.75 in (17.1 x 32.4 cm) | Same |
| Fiber optic Blanket Materials | Polyvinyl Chloride (PVC) | Polyvinyl Chloride (PVC) | Same  
Note: the materials of the Blanket Pad are not patient contacting. |
| Fiber optic cable sheath material | Silicone tubing | Vinyl tubing | Vinyl accommodates the high frequency welding required for high frequency welded joint and does not accumulate dust as silicone does |
| Blanket Mattress | Polyurethane cover with polyolefin bubble cushioning | Polyurethane cover with polyolefin bubble cushioning | Same  
Note: The materials of the mattress are not intended for patient contact. |
| Disposable Mattress Cover | Non-woven polypropylene | Non-woven polypropylene | Same  
Note: the materials of the mattress cover are patient contacting |
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<tbody>
<tr>
<td>Adjustable light output</td>
<td>Yes – adjustable to ≥55 µW/cm²/nm</td>
<td>Yes - adjustable to 50 to 60 µW/cm²/nm.</td>
<td>There were no design changes made to the light box. The upper limit was added to the specification to align with the AAP Guidelines.</td>
</tr>
<tr>
<td>Thermal Monitoring Circuit</td>
<td>One temperature sensor - temperature sensor installed to detect overheating condition of the LED.</td>
<td>Two temperature sensors - one temperature sensor installed to detect overheating condition of the LED, and one to detect a pending overheating condition of internal lens interface</td>
<td>The addition of the additional sensor does not raise questions about the safety or effectiveness of the updated device. The additional sensor indicates if the pad is approaching the end of useful life.</td>
</tr>
<tr>
<td>Optic lens</td>
<td>Acrylic lens</td>
<td>Glass lens</td>
<td>Provides more consistent and efficient light transmission from the LED to the fiber optic cable</td>
</tr>
<tr>
<td>Adhesive material used to bond fiber optics together inside tip of fiber optic cable</td>
<td>Two component epoxy</td>
<td>UV cured optical adhesive</td>
<td>The new adhesive material is longer lasting and more durable than the two part epoxy and improves reliability.</td>
</tr>
<tr>
<td>Connection of the fiber optic cable to the light box</td>
<td>No handle</td>
<td>New handle grip</td>
<td>The addition of a handle grip does not raise questions about the safety or effectiveness of the updated device. It aids in the ease of connection and increased durability.</td>
</tr>
<tr>
<td>Pad/tubing connection</td>
<td>Heat shrink tubing</td>
<td>High frequency welded joint</td>
<td>Welded joint eliminates crevices and folds in the joint for ease of cleaning</td>
</tr>
<tr>
<td>Power Supply to Light Box</td>
<td>Mains powered: 100-240 Volts at either 50 or 60 Hz. This external power supply provides 12 VDC to the light box</td>
<td>Mains powered: 100-240 Volts at either 50 or 60 Hz. This external power supply provides 12 VDC to the light box</td>
<td>Same</td>
</tr>
</tbody>
</table>
No design changes were made to the device with respect to intensity output, however, the intensity specification statements were updated to ensure design inputs were clear and unambiguous, and to align the statements with the recommendations of the American Association of Pediatrics. The design changes made to the device were intended to improve the reliability and usability of the neoBLUE blanket, thus increasing the lifetime of the device. These differences do not raise any different questions of safety or effectiveness.

Clinical Tests: N/A

Nonclinical Tests:

Design verification and validation were performed to ensure that the neoBLUE blanket LED Phototherapy System meets its performance specifications and demonstrates equivalence to the specified predicate device, including specific testing for device power, electrical safety, indicators, LED performance, intensity levels, intensity range, effective area, and usability.

Where appropriate, testing was performed to recognized standards, including:


- Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances –
Conclusions:

The verification and validation summary and risk analysis documentation provided in this 510(k) support the conclusion that the neoBLUE blanket LED Phototherapy system is as safe and as effective as the predicate device cleared under K103259 and determined to be substantially equivalent.