October 27, 2017

NeoLight, LLC
% Paul E. Dryden
Regulatory Consultant
ProMedic, LLC
24301 Woodsage Drive
Bonita Springs, Florida 34134-2958

Re: K170585
Trade/Device Name: Skylife™
Regulation Number: 21 CFR 880.5700
Regulation Name: Neonatal phototherapy unit
Regulatory Class: Class II
Product Code: LBI
Dated: September 23, 2017
Received: September 26, 2017

Dear Paul E. Dryden:

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 (DICE) 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 (DICE) 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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K170585

Device Name

Skylife™

Indications for Use *(Describe)*

Skylife™ is intended for the treatment of neonatal unconjugated hyperbilirubinemia. It is designed to provide phototherapy treatment from underneath the baby. Skylife™ must be used within a patient enclosure, such as a bassinet, an open crib, a warming table or an incubator. Skylife™ can be used in a clinical setting or in the home.

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

XX 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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Date Prepared October 25, 2017

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3 – DEVICE CLASSIFICATION

Trade/Proprietary Name:	Skylife™
Common Name:	Neonatal phototherapy device unit
Classification Name:	Neonatal phototherapy
Regulation:	(21 CFR 880.5700)
Product Code:	LBI
Regulatory Class:	II

4 – PREDICATE DEVICES

Primary Predicate:	K051869 – neoBLUE cozy LED Phototherapy System, Natus Medical, Inc.
Secondary Predicate:	K011549 – Ohmeda Medical Spot PT Lite Phototherapy System, Ohmeda Medical

5 - DEVICE DESCRIPTION

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

Skylife™ utilizes blue LEDs to achieve intensities from 25 μW/cm^2/nm to >55 μW/cm²/nm, emitting light in a narrow bandwidth between 430-475 nm. This light bandwidth corresponds to the spectral absorption of light by bilirubin. Skylife™ utilizes blue LEDs in this range to achieve peak intensities between 25 to 35, 35 to 55, and over 55 μw/cm²/nm at low, high, and very high settings. Skylife™ at the Very High setting provides an average intensity of 56.3 μw/cm^2/nm over the treatment area with peak at 72.4 μw /cm^2/nm.

Treatment is intended to be applied until the bilirubin levels have dropped sufficiently that the child no longer suffers from jaundice. Phototherapy treatment of neonatal jaundice using Skylife™ can be applied at home or in a hospital.

Skylife™ consists of the following components: Light bed and light modules, GelMat, disposable mattress cover (Cloud Swaddle), controller, and power supply.

6 - INDICATIONS FOR USE

Skylife™ is intended for the treatment of neonatal unconjugated hyperbilirubinemia. It is designed to provide phototherapy treatment from underneath the baby. Skylife™ must be used within a patient enclosure, such as a bassinet, an open crib, a warming table, or an incubator. Skylife™ can be used in a clinical setting or in the home.

7 - COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICES

The intended use, design, materials, and functional characteristics of Skylife™ and the predicate device are substantially equivalent. The subject device and predicate device provide phototherapy for treatment of neonatal unconjugated hyperbilirubinemia (jaundice), are portable, and intended for home and healthcare environment use. Both devices use the same operating principle to deliver light to degrade bilirubin. In both devices, the user (caregiver) selects the desired treatment intensity as prescribed by a physician.

The following table summarizes the technological characteristics of the subject device and predicate devices.:

Features	**Subject Device- Skylife™**	**Primary Predicate Device- neoBLUE cozy LED Phototherapy System - K051869**	**Secondary Predicate Device- Ohmeda Medical Spot PT Lite Phototherapy System - K011549**
Intended Use	Treatment of neonatal hyperbilirubinemia	Similar to the subject device	Similar to the subject device
Indications for use	Skylife™ is intended for the treatment of neonatal unconjugated hyperbilirubinemia. It is designed to provide phototherapy treatment from underneath the baby. Skylife™ must be used within a patient enclosure, such as bassinet, an open crib, a warming table or an incubator. Skylife™ can be used in a clinical setting or in the home.	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 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.	The Spot PT Lite Phototherapy System provides light therapy for the treatment of hyperbilirubinemia, commonly known as neonatal jaundice, during the newborn period in the hospital.
Treatment modes	Under-baby phototherapy	Under-baby phototherapy	Overhead neonatal, phototherapy device
Targeted population	Neonates	Neonates	Neonates
Sites of use	Clinical setting and home use	Clinical setting and home use	Clinical setting
Specifications			
Type of device	Free standing device	Free standing device	Overhanging device
Type of light	Blue light LED	Blue light LED	White metal halide Bulb
Intensity	25-35 µW/cm^2/nm, Low setting 35-55 µW/ cm^2/nm, High setting >55 µW/ cm^2/nm, Very high setting	30 – 35 µW/ cm^2/nm	57.6 µW/ cm^2/nm ± 25%
Height	4.86 cm (1.913 in)	≤ 12.7 cm (5.0 in)	Variable
Width and length	60.80 cm x 31.12 cm (23.94 in x 12.25 in)	30.5 cm x 64.8 cm (12 in x 25.5 in)	20 cm x 30 cm (7.9 in x 11.8 in)
Weight	<4.99 kg (<11 lbs)	< 4.3 kg (9.5 lbs)	4.2 kg (9.26 lbs)
Treatment area	769 cm^2 (119.2 in^2)	Minimum 613 cm^2 (95in^2)	315 cm^2 (48.8 in^2)
Materials			
Device/ bed	ABS bed casing with acrylic sheet	Polycarbonate cover and polyurethane base	Not Applicable
Mattress (gel mat)	Polyurethane cover filled with polyurethane gel	Polyurethane cover with polyolefin bubble cushioning	Not Applicable
Mattress cover	Polypropylene fabric - disposable	Nonwoven spunlaced polyester - disposable	Not Applicable
Patient side cushioning	Polyester fiber cushion with polypropylene fabric foot bumper and restrainers	Foam bumper encased by 100% cotton fabric	Not Applicable

Features	Subject Device- Skylife™	Primary Predicate Device - neoBLUE cozy LED Phototherapy System - K051869	Secondary Predicate Device - Ohmeda Medical Spot PT Lite Phototherapy System - K011549
Miscellaneous			
Shape	Rectangular	Oval with flat end at foot area	Rectangular with Goose neck for overhead treatment
Portable	Portable	Portable	Requires a structure for installation
Patient side	Polyester fiber cushion with polypropylene fabric foot bumper and restrainers	Foam bumper encased by 100% cotton fabric	Overhead Device; no patient contact
Applicable standards and Safety Features			
Electrical safety	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-50	EN 60606-1 UL 2601-1 EaveN 60606-1 CSA C22.2 601.1 EN 60601-2-50	IEC 60601-1-2:2004; UL 60601-1:2003: IEC 60601-1:1998: CAN/CSA 601-1M90 Self-certified to IEC 60601-2-50, 2000
Mechanical safety	Disposable cover Mattress acts as diffuser to minimize accidental viewing of single point light source. Disposable cover has restrainers to restrict patient's movement	Disposable cover Plastic diffuser acts as a diffuser to minimize accidental viewing of single point light source	Overhead device; No patient contact and always to be used with eye mask
Thermal safety	Fan to cool circuitry, minimize device heating. Thermal protection circuit - turns off LEDs if the device gets too warm.	Fan to cool circuitry, minimize device heating. Thermal protection circuit - turns off LEDs if the device gets too warm.	Has fan at bottom of the device for cooling circuitry; Continuous monitoring required when used with warming tables, incubator and radiant warmers
Radiation safety	LED light source emits no significant ultraviolet light	LED light source emits no significant ultraviolet light	Light source does not emit any significant ultraviolet light
Ingress of liquids	IP23	IPX4	Not Applicable
Human Factors			
Controls and Indicators	On/Off switch. Indicators Overheat High/Low intensity light	On/Off switch. Indicators Overheat High/Low intensity light	On/Off switch. Indicators Overheat
Compatibility with environment and other devices	Used inside bassinet, open crib, warmer table, incubator	Used inside bassinet, open crib, warmer table, incubator	Used along with bassinet, open crib, warmer table, incubator: Requires a support structure to mount

8 – DISCUSSION OF DIFFERENCES

Skylife™ specifically differs from the neoBLUE cozy Phototherapy System and Spot PT Lite Phototherapy System in the following areas:

	Subject device, Skylife™ System	**Primary Predicate Device - neoBLUE cozy LED Phototherapy System - K051869**	**Secondary Predicate Device - Ohmeda Medical Spot PT Lite Phototherapy System - K011549**	**Discussion**
Total number of LEDs/light	14	480	No LEDs, a metal halide bulb	**Differences between the subject and the predicate devices:** The construction of the device does not raise any questions related to safety and efficacy, since both the subject and predicates deliver light intensities in the similar ranges, at the patient's skin, to treat neonatal unconjugated hyperbilirubinemia.
LED/light location	Two modules placed on the bed sides	Placed on one single panel	Above the bed on an adjustable gooseneck	
Light orientation	Emitted upwards from sides of light bed	Emitted upwards from center of the bed	Emitted downwards from above towards the patient	
Light intensity level	Three levels; Low, High, and Very High	One level	One level	
Wavelength	430 – 475 nm 453 – 460 nm (typical peak)	400 – 500 nm 450 – 475 nm (typical peak)	350 – 700 nm 570 – 590 (typical peak)	**Differences between the subject and the predicate devices:** Wavelength range and peak wavelengths overlap. Hence this does not raise any questions for safety and efficacy.

Light intensity range	25-55 and >55 µw/ cm²/nm (avg 56.3 µw/ cm²/nm, max 72.4 3 µw/ cm²/nm)	30 – 35 µW/cm^2/nm	57.6 µW/cm^2/nm ± 25% (43.2 – 72 µW/cm^2/nm)	**Differences between the subject and predicates:** The subject device has an intensity range 25-55 and >55 µw/cm²/nm. This range is higher than the range of the predicates, and i which have an upper intensity range of 72 µw/cm²/nm, based upon their specification. This difference does not raise new questions of safety or effectiveness for the subject device.

The differences in the technological characteristics between Skylife™ and the predicate device do not raise new issues of safety or effectiveness.

9 - PERFORMANCE DATA

The following performance tests were performed. These included:

- Electrical safety and electromagnetic compatibility
- Biocompatibility of patient contacting materials
- Human Factors Usability

Skylife™ was tested per the following standards:

- IEC 60601-1: 2005, 3rd Edition, Medical Electrical Equipment- Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2: 2014, 4th Medical Electrical Equipment- Part 1-2: General requirements for basic safety and essential performance —Collateral standard: Electromagnetic compatibility — Requirements and tests
- IEC 60601-2-50: 2009, 2nd Edition, Medical Electrical Equipment- Part 2-50: Medical electrical equipment - Part 2-50: Particular requirements for the safety of infant phototherapy equipment
- IEC 60601-1-11: 2015, 2nd Edition, Medical Electrical Equipment- Part 1-11: General requirements for basic safety and essential performance- Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
- IEC 60601-1-6: 2010, 3rd Edition, General requirements for basic safety and essential performance – Collateral standard: Usability
- IEC 62366:2007, 1st Edition, Medical devices -- Application of usability engineering to medical devices

- IEC 60601-1-8: 2006, Medical electrical equipment -- Part 1-8: General requirements for basic safety and essential performance -- Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems

Biocompatibility of Materials –

ISO 10993-1 specifies the patient contacting materials as Surface Contact, Skin, Prolonged Contact (> 24 hours, < 30 days)

Testing included:

- ISO 10993-5:2009, Biological evaluation of medical devices- Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10:2010, Biological evaluation of medical devices- Part 10: Tests for irritation and skin sensitization

Discussion – The materials tested were found to be non-cytotoxic, non-sensitizers, and non-irritants.

Human Factors and Usability -

The human factors and usability study was conducted with 2 user groups to validate the usability of Skylife™ in a healthcare and home environment. The results of the study support the instructions for successfully using the device as intended. The results of human factors and usability study substantiates the acceptability of the risks identified during the risk assessment activities.

10 – SUBSTANTIAL EQUIVALENCE CONCLUSION

Based on the performance testing and the supporting documentation, it can be concluded that Skylife™ is substantially equivalent to the predicate devices.