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

October 6, 2017

Neomedlight
Pierre Girons
CEO
89-90 Rue Frederic Fays
Villeurbanne, 69100
FRANCE

Re: K163526
Trade/Device Name: Bilicocoon™ Phototherapy System
Regulation Number: 21 CFR 880.5700
Regulation Name: Neonatal Phototherapy Unit
Regulatory Class: Class II
Product Code: LBI
Dated: August 29, 2017
Received: September 1, 2017

Dear Pierre Girons:

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,

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)*
K163526

Device Name
BiliCocoon™ Phototherapy System

Indications for Use *(Describe)*
The BiliCocoon™ Phototherapy System is intended for the treatment of unconjugated hyperbilirubinemia in the population of neonates and infants under 3 months old and weighing less than 10kg. It can be used in the clinical setting or in the home

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."

K163526 510(K) SUMMARY

Manufacturer's Name:	NEOMEDLIGHT 89-90 Rue Frederic FAYS 69100 Villeurbanne France Ph.: +33 6 33 902 900
Corresponding Official:	Pierre SAINT-GIRONS CEO
Telephone Number:	+33 6 33 902 900
E-mail:	pierre.saintgirons@neomedlight.com

Preparation Date:	October 3, 2017
Trade Name:	BiliCocoon™ Phototherapy System
Common or Usual Name:	Neonatal phototherapy unit
Regulation Name:	Unit, Neonatal Phototherapy
Regulation Number:	21 CFR 880.5700
Product Code:	LBI : unit, neonatal phototherapy PDH : blanket, neonatal phototherapy
Device Class:	Class II
Primary Predicate Device:	K103589, neoBLUE® blanket LED Phototherapy System

Device Description

The BiliCocoon™ Phototherapy System is a phototherapy system designed to treat unconjugated hyperbilirubinemia in newborns and infants under 3 months old and weighing less than 10kg. It is a phototherapy device, which emits light in the absorption spectrum of the bilirubin, from 430 to 490 nm. A custom optic directs light from the LEDs into the fiberoptic Pad. The system is composed of a blue light electronic generator – the Light Box – and of a light emitting fabric – the Pad – which transmits the blue light to the newborn. The Pad is provided in two versions: Bag Pad and Nest Pad. The Light Box has a user interface to set the session time and inform the user about eventual errors. The other parameters of the therapy (irradiance level, light wavelength, etc.) are fixed.

The BiliCocoon™ Phototherapy System is used with the BiliCocoon™ Disposable, a non-woven disposable designed to fit the Pad which interfaces between the Pad and the newborn. The disposable is the only part which contacts the newborn skin.

The BiliCocoon™ Phototherapy System can be fixed on the BiliCocoon™ Fixation system.

Indications for Use

The BiliCocoon™ Phototherapy System is intended for the treatment of unconjugated hyperbilirubinemia in the population of neonates and infants under 3 months old and weighing less than 10kg. It can be used in the clinical setting or in the home.

The device is prescription only.

Substantial Equivalence Discussion

The table below includes a comparison of the technological characteristics between the new device and those of the predicate device:

Characteristic	**Predicate Device** neoBLUE blanket LED Phototherapy System, K103589	**Subject Device** BiliCocoon™ Phototherapy System K163526	**Comments**
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.	The BiliCocoon™ Phototherapy System is intended for the treatment of unconjugated hyperbilirubinemia in the population of neonates and infants under 3 months old and weighing less than 10kg. It can be used in the clinical setting or in the home.	Different – see Comment 1
Population	Neonates	Neonates and infants under 3 months and 10kg	Different – see comment 1
Treatment Method	Underneath blue light	Nest Pad : Underneath blue light Bag Pad : Underneath and above blue light	Different – See Comments 2, 4
Sites of use	Clinical, Home Use	Clinical, Home Use	Same
Type of Device	Portable	Portable	Same
Technological Features			
Type of Blue light	Blue Led Light with peak emission between 450 and 475 nm	Blue Led Light with peak emission between 430 and 490 nm	Different – See Comment 2
Intensity (irradiance) average	30 - 35 μW/cm²/nm	30 - 40 μW/cm²/nm	Different – See Comment 2
Connection	1 bundle of optical fiber (diameter 1.8 cm)	6 bundle of optical fiber (diameter 0.75cm)	Different – See Comment 3
Power Supply	12 VCC / 8.3A 100W	12 VCC / 7.5A 90W	Different – See Comment 3
Power Security	double insulation class I	double insulation class II	Different – See Comment 3
Leakage Current	<100μA	<100μA	Same
Light Box			

Dimensions	11.4 cm x 22.9 cm x 14.0 cm	21.5 cm x 19.8 cm x 16.0 cm	Similar
Weight	1.5 kg	1.4 kg	Similar
PAD Treatment Area			
light emitting area	Small Blanket : 819 cm² Large Blanket : 542 cm²	Nest Pad : 1200 cm² Bag Pad : 1200 cm²	Different – See Comment 4
effective treatment area according to IEC 60601-2-50	Small Blanket : 504 cm² Large Blanket : 296 cm²	Nest Pad : 1200 cm² Bag Pad : 1200 cm²	Different – See Comment 4
PAD Materials	Polyurethane (mattress covering the fiber optics PAD)	Polyurethane (mattress covering the fiber optics PAD)	Same
Use Intent	Multiple Patients	Multiple Patients	Same
Disposable Blanket			
Use Intent	Single Patient	Single Patient	Same
patient contact	Non-woven polypropylene	Nonwoven Polypropylene/Polyester-Viscose	Different – See Comment 5
Alarms			
Bad optical connection	Yes	Yes	Same
LED overheating	Yes	Yes	Same
LED Control	Yes	Yes	Same
Noise	25dB	35dB	Similar
Timer	No	Yes	Different – See Comment 6

Comment 1

The predicate device is intended for the treatment of hyperbilirubinemia in the neonate population. Hyperbilirubinemia in neonates is a common pathology which is characterized by an augmentation of circulating bilirubin. Hyperbilirubinemia is commonly associated to unconjugated hyperbilirubinemia because it is the most common pathology creating an augmentation of bilirubin. Phototherapy is a method to treat unconjugated hyperbilirubinemia by transforming bilirubin into water-soluble isomers that can be eliminated without conjugation in the liver.

The subject devices restricts the intended use to unconjugated hyperbilirubinemia which is the most common form of hyperbilirubinemia. Conjugated hyperbilirubinemia is rare and not treated by phototherapy, therefore a phototherapy device intended to treat hyperbilirubinemia is essentially referring to unconjugated hyperbilirubinemia. Intended use of Bilicocoon™ Phototherapy System is thus equivalent to the intended use of the predicate device.

The claimed targeted population is also different but this difference does not bring any additional risk. Neonates are defined by the Agency as birth to 28 days. However, the chosen the targeted population is up to 3 months and 10kg. This will not change the risk, as an older and heavier population is less critical.

Comment 2

Both devices use the same principle – blue light, peak emission in the wavelength range 430-490nm and irradiance >30µW/cm²/nm – recommended by the American Academy of Pediatrics for intensive phototherapy treatment. The difference in the light peak emission, irradiance and surface area for treatment does not raise new or different questions of safety or effectiveness.

Comment 3

The connector of the BiliCocoon™ Phototherapy System is based on the same technologies than the predicate, except that the subject device employs solutions to prevent overheating and fiber degradation due to heat. The same electrical safety and performance testing was performed for both the subject and predicate device.

Comment 4

There are no relevant differences in the therapy, except that the subject device enables to cover a larger portion of the body surface of the infant, by providing larger fiber optic pads and the possibility of illuminating from underneath and above the patient. The American Academy of Pediatrics recommends covering as much as possible the body surface of the infant for phototherapy treatment. Therefore the differences in treatment area do not raise new or different questions of safety or effectiveness.

Comment 5

The predicate device disposable component material is non-woven polypropylene. The BiliCocoon™ Phototherapy System disposable is non-woven polypropylene /polyester viscose. Both devices underwent the same biocompatibility tests per ISO 10993 for the patient contacting materials and met the same requirements; thereby these are substantially equivalent.

Comment 6

The predicate software and the BiliCocoon™ Phototherapy System software remain linked to the microcontroller, without any communication, interpretation or data exchange feature. The user interface for the BiliCocoon™ Phototherapy System adds a screen and navigation button to set up a timer, but is not adding any risks as both the predicate device and the subject device can be switched off manually and safely at any time.

Performance Testing

The following bench testing was performed and reviewed to support the substantial equivalence of the subject device:

- Biocompatibility tests performed per ISO 10993 for patient contacting materials (disposable cover).
    - The disposable cover is considered a skin-contacting device with prolonged exposure
        - Cytotoxicity per ISO 10993-5, USP 87
        - Intracutaneous irritation Study per ISO 10993-10
        - Sensitization per ISO 10993-10, USP 88
- Bench tests performed to measure spectral output, light irradiance and effective surface treatment area.
- Electrical safety tests performed per IEC 60601-1 (3rd edition A1:2012)
- Electromagnetic Compatibility tests (EMI/EMC) performed per IEC 60601-1-2 (4th edition).
- Phototherapy safety and performance tests performed per IEC 60601-2-50 (2nd edition).
- Home Use has been assessed per IEC 60601-1-11 (2nd edition:2015) and the FDA Guidance, "Applying Human Factors and Usability Engineering to Medical Devices"
- Photobiological safety assessed with IEC 62471.
- Cleaning Validation Testing

There is no difference of non-clinical testing performed between the device under submission and the predicate device.

Clinical Tests

Not Applicable

Conclusions

The differences between the predicate and the subject device do not raise any new or different questions of safety or effectiveness. The BiliCocoon™ Phototherapy System is substantially equivalent to the NeoBLUE blanket LED Phototherapy System cleared under K103589 with respect to the indications for use, target populations, treatment method, and technological characteristics.