October 5, 2020

Avalon Biomedical (Shenzhen) Limited
Eva Zhu
Regulatory Affairs Manager
805 Building 4, Yinxing Zhije, 1301-74, GuanGuang Road,
XinLan Community
Shenzhen, 518110
China

Re: K200031
Trade/Device Name: Neonatal Phototherapy System, Model: KANGALITE
Regulation Number: 21 CFR 880.5700
Regulation Name: Neonatal Phototherapy Unit
Regulatory Class: Class II
Product Code: LBI
Dated: August 31, 2020
Received: September 3, 2020

Dear Eva Zhu:

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 801); 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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Payal Patel
Acting Assistant Director
DHT3C: Division of Drug Delivery and
General Hospital Devices,
and Human Factors
OHT3: Office of Gastrorenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K200031

Device Name
Neonatal Phototherapy System, Model: KANGALITE

Indications for Use *(Describe)*
The Neonatal Phototherapy System, Model: KANGALITE is intended for the treatment of unconjugated hyperbilirubinemia in the population of neonates: gestational age ≥38 weeks and weight within 2500-4500 grams. It can be used in the clinical setting or in the home environment. It should be used for neonates whom phototherapy has been prescribed.

Contraindication

The Neonatal Phototherapy System, Model: KANGALITE should NOT be used in cases of:
(a) Congenital porphyria or a family history of porphyria
(b) Concomitant use of drugs or agents that are photosensitizers
A use that does not take into account these contraindications may lead to an ineffective treatment or to potential risks to the patient's health.

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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510(k) Summary

K200031

The following 510(k) summary has been prepared pursuant to requirements specified in 21 CFR 807.92:

Date: October 5, 2020

1. Submitter:

Submitter: Avalon Biomedical (Shenzhen) Limited
Address: 805, Building 4, Yinxing Zhijie, 1301-74, GuanGuang Road, XinLan Community, GuanLan Street, Longhua District, 518110, Shenzhen, China
Contact Person: Eva Zhu, Regulatory Affairs Manager
Phone: +86 755 2107 0534
Email: zhul@avalonbiomedical.com

2. Device Name

Trade or Proprietary Name: Neonatal Phototherapy System, KANGALITE™
Common or Usual Name: Neonatal Phototherapy System
Classification Name: Neonatal phototherapy unit
Device Class: II
Product Code: LBI
Panel: General Hospital
Regulation Number: 21 CFR 880.5700

3. Predicate Device:

510(k) Number: K070180
Device Name and Model: Bili-Tx
Manufacturer Name: Respironics Inc.

4. Indications for Use:

The Neonatal Phototherapy System, Model: KANGALITE is intended for the treatment of unconjugated hyperbilirubinemia in the population of neonates: gestational age ≥38 weeks and weight within 2500-4500 grams. It can be used in the clinical setting or in the home environment. It should be used for neonates whom phototherapy has been prescribed.

Contraindication

The Neonatal Phototherapy System, Model: KANGALITE should NOT be used in cases of:
(a) Congenital porphyria or a family history of porphyria
(b) Concomitant use of drugs or agents that are photosensitizers
A use that does not take into account these contraindications may lead to an ineffective treatment or to potential risks to the patient's health.

5. Device Description:

The Neonatal Phototherapy System, Model: KANGALITE is a wearable phototherapy system that consists of six components: Light Source with AC Power Cord, Dual Fiber Optic Panels (Standard accessory) /Single Fiber Optic Panel (optional accessory), Swaddle, Shoulder Strap, Disposable Covers and *Table Mounting Clip (optional accessory)*. The Neonatal Phototherapy System, Model: KANGALITE delivers a narrow band of high-intensity blue light via a blue light emitting diode (LED), in order to provide phototherapy treatment for neonatal hyperbilirubinemia.

The Neonatal Phototherapy System, Model: KANGALITE Light Source contains a blue LED which emits light in the range 400–500 nm (peak wavelength 455±10 nm). The system gives only one blue light irradiance output level which is not adjustable. This blue light is directed through the optical fiber bundle to the illuminating area of the Fiber Optic Panel where the newborn receives blue light therapy.

The Fiber Optic Panel is inserted into the Disposable Cover and is placed in a soft and comfortable Swaddle, while the baby is wrapped inside to receive phototherapy. Baby is allowed to receive kangaroo care. Besides, compare to conventional phototherapy, no eye protection for the baby is required as blue light will not leak out when properly set up.

The light output (>30 μW/cm^2/nm) is sufficient to provide intensive phototherapy which is defined

as in the American Academy of Pediatrics (AAP) standard.

Average irradiance for:

Dual Fiber Optic Panels: 50 μW/cm^2/nm (±25%);

Single Fiber Optic Panel: 60 μW/cm^2/nm (±25%).

The spectrum range of the blue LED light matches with the spectral absorption of bilirubin. Under blue light irradiation, subcutaneous bilirubin absorbs strongly in the blue region of the light spectrum and converts into less lipophilic waste products which can be excreted through the bile or urine without the need for conjugation.

The Neonatal Phototherapy System, Model: KANGALITE can be directly connected to nominal voltages readily available throughout the world as the Light Source is affixed with a wide-range medical adaptor, rated from 100–240 VAC and 50/60 Hz. It converts the power to 15 VDC to power up the Light Source.

Environment:
Operating temperature/humidity: 59 to 95 °F (15 to 35 °C)/15 to 95 %RH, non-condensing
Storage temperature/humidity: -4 to 122 °F (-20 to 50 °C) /15 to 95 %RH, non-condensing
Atmospheric pressure: 700–1060 hPa

6. Comparison of technological characteristics with the predicate device

Comparison Table

Device name	**Subject device** **Neonatal Phototherapy System** **Model: KANGALITE** **K200031**	**Predicate device** **Bili-Tx** **K070180**	**Comparison**
Manufacturer	**Avalon Biomedical (Shenzhen) Limited**	Respironics Inc.	N/A
Regulation No.	880.5700	880.5700	same
Product Code	LBI	LBI	same
Classification	II	II	same

Device name	Subject device Neonatal Phototherapy System Model: KANGALITE K200031	Predicate device Bili-Tx K070180	Comparison
Indications for use	The Neonatal Phototherapy System, Model: KANGALITE is intended for the treatment of unconjugated hyperbilirubinemia in the population of neonates: gestational age ≥38 weeks and weight within 2500-4500 grams. It can be used in the clinical setting or in the home environment. It should be used for neonates whom phototherapy has been prescribed. Contraindication The Neonatal Phototherapy System, Model: KANGALITE should NOT be used in cases of: (a) Congenital porphyria or a family history of porphyria (b) Concomitant use of drugs or agents that are photosensitizers A use that does not take into account these contraindications may lead to an ineffective treatment or to potential risks to the patient's health.	The Bili-Tx is intended to treat hyperbilirubinemia through phototherapy in a home or hospital/institutional environment.	Different See comment 1
Contraindications	1. Congenital porphyria or a family history of porphyria 2. Concomitant use of drugs or agents that are photosensitizers	There is no publicly-available information.	Different See comment 1

Device name	Subject device Neonatal Phototherapy System Model: KANGALITE K200031	Predicate device Bili-Tx K070180	Comparison
Principle of operation	KANGALITE treats neonatal hyperbilirubinemia via blue light phototherapy. The device delivers a narrow band of high-intensity blue light via a blue light emitting diode (LED). Under blue light irradiation, subcutaneous bilirubin absorbs strongly in the blue region of the light spectrum and converts into less lipophilic waste products which can be excreted through the bile or urine without the need for conjugation.	The Bili-Tx phototherapy system uses blue light emitting diodes (LEDs) to convert bilirubin to waste products that are mostly excreted through urine and stool, thus reducing the bilirubin level in the baby's blood.	Same
Patient contact materials (Patient is in supine position)	1. Swaddle, the material in contact with patient's body skin is made of 100% cotton 2. Disposable Cover, the material in contact with patient's chest and back skin is made of non-woven polypropylene 3. Dual Fiber Optic Panels, the material in contact with patient's chest and back skin is made of TPU 4. Single Fiber Optic Panel, the material in contact with patient's back skin is made of TPU	There is no publicly-available information.	Different See comment 2
Targeted population	Neonates: gestational age ≥38 weeks and weight within 2500-4500 grams.	Neonates	Different See comment 3
Prescription Use	Yes	Yes	Same
Over-The-Counter Use	No	No	Same

Device name	Subject device Neonatal Phototherapy System Model: KANGALITE K200031	Predicate device Bili-Tx K070180	Comparison
Site of use	In the clinical setting or in the home	In the clinical setting or in the home	Same
Treatment mode	Use with Fiber Optic Panel	Two different modes 1) Use with Fiber Optic Panel 2) Overhead treatment	Different See comment 4
Device Components	1. Light Source (with AC power cord) 2. Dual Fiber Optic Panels (Standard accessory) / Single Fiber Optic Panel (optional accessory) 3. Swaddle (One size) 4. Shoulder Strap 5. Table Mounting Clip (optional accessory) 6. Disposable Cover × 2 (single-use)	With Fiber Optic Panel: 1. Illuminator device with AC power cord 2. Fiber Optic Panel 3. Disposable Cover *4. Illuminator device carrying case (optional)* *5. System Carrying Case (optional)* Other components from overhead phototherapy 6. Mounting brace 7. Circuit support arm 8. Circuit support adaptor	Similar See comment 5
Eye protection for the baby is required during treatment	No	No	Same
If Eye Shield includes in the accessories list	No	No	Same
TECHNOLOGICAL FEATURES			

Device name	Subject device Neonatal Phototherapy System Model: KANGALITE K200031	Predicate device Bili-Tx K070180	Comparison
Light Source	Single blue LED	Uses blue light emitting diodes (LEDs)	Similar See comment 6
Treatment Wavelength	Blue LED: 400–500 nm Peak: 455 ± 10 nm	Blue LEDs emit light in the range of 400–550 nm (peak wavelength 450–470 nm).	Similar See comment 6
Light Intensity (Irradiance)	Dual Fiber Optic Panel irradiance level: 50 μW/cm²/nm (± 25%) Single Fiber Optic Panel irradiance level: 60 μW/cm²/nm (± 25%)	Standard Panel-Light: 30 μW/cm²/nm Neonatal Panel-Light: 55 μW/cm²/nm Overhead Therapy: When the illuminator is positioned 30 cm (12 inches) above the neonate: 30 μW/cm²/nm	Similar See comment 6
Expected LED life	Nominal lifetime: >45000 hours	Minimum lifetime of 30,000 hours	Different See comment 7
Connection of the Fiber optic bundle to Light Source	Direct insert with a “click” sound	Insert and rotate a quarter turn	Different See comment 8
Power Supply to Light Box	AC Power: 100–240 VAC, 50/60 Hz, 1.0–0.5 A	AC Power: 100–240 VAC, 50/60 Hz, 1.0 A	Same
Timer	Yes	Yes	Same
LIGHT BOX/ LIGHT SOURCE			
Light box dimensions	7.5 cm × 7.7 cm × 15.9cm (Light Source)	16.10 cm × 7.40 cm (Illuminator)	Similar See Comment 9

Device name	Subject device Neonatal Phototherapy System Model: KANGALITE K200031	Predicate device Bili-Tx K070180	Comparison
Weight	< 1.5 kg	< 2.50 lb (1. 3 kg)	
FIBER OPTIC PANEL AND SWADDLES			
Fiber optic panel Dimensions and effective treatment area according to IEC 60601-2-50	Dual Fiber Optic Panels: size of effective illuminated area: 16.0 cm × 12.0 cm × 2 = 384 cm^2 Single Fiber Optic Panel: size of effective illuminated area: 16.0 cm × 12.0 cm = 192 cm^2	**Model: EG-2000N (Flat Neonatal Panel)** Overall Pad Size-Neonatal: 5.00" × 7.00" (12.70 cm × 17.78 cm) Illuminated Area-Neonatal: 4.00" × 6.00" (10.16 cm × 15.24 cm) = 155 cm^2 **Model: EG-2000 (Wrap Around Panel)** Overall Pad Size-Standard: 4.00" × 15.00" (10.16 cm × 38.10 cm) Illuminated Area-Standard: 3.00" × 14.00" (7.62 cm × 35.56 cm) = 271 cm^2	Similar See Comment 10
Swaddle	100% cotton	N/A	Different See comment 11
PAD TREATMENT AREA			
Panel material with direct contact to patient	TPU	TPU	Same
Use Intent	Multiple patients	Multiple patients	Same
NOISE			
Noise	< 60 dB(A)	< 60 dB (A)	Same

Device name	Subject device Neonatal Phototherapy System Model: KANGALITE K200031	Predicate device Bili-Tx K070180	Comparison
STANDARDS COMPILED			
Biocompatibility test	Biocompatibility tests performed per ISO 10993 for patient contacting materials (Disposable cover and Swaddle). Both the Disposable cover and Swaddle are considered a skin-contacting device with prolonged exposure. Cytotoxicity per ISO 10993-5 Intracutaneous irritation study per ISO 10993-10 Sensitization per ISO 10993-10	There is no publicly-available information.	Different See comment 12
Electrical safety tests	IEC 60601-1 General requirements for basic safety and essential performance	IEC 60601-1 General Requirements for Safety of Medical Electrical Equipment	Same
Electromagnetic Compatibility tests (EMI/EMC)	Electromagnetic Compatibility tests (EMI/EMC) performed per IEC 60601-1-2 (4th edition)	Electromagnetic Compatibility tests (EMI/EMC) performed per EN 60601-1-2 (2nd edition)	Same
Phototherapy safety and performance tests	IEC 60601-2-50 Particular requirements for the basic safety and essential performance of infant phototherapy equipment	IEC 60601-2-50 Particular requirements for the basic safety and essential performance of infant phototherapy equipment	Same

Device name	Subject device Neonatal Phototherapy System Model: KANGALITE K200031	Predicate device Bili-Tx K070180	Comparison
Home Use	Intended for home and hospital use: IEC 60601-1-11 General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment	. The Bili-Tx is intended to treat hyperbilirubinemia through phototherapy in a home or hospital/institutional environment.	Same See comment 13
Ingression of water for Light Source	IP22	IPX0	Different See comment 14

7. Discussion:

Comment 1

The subject device, Neonatal Phototherapy System, Model: KANGALITE, restricts the intended use to a specific weight of neonates and unconjugated hyperbilirubinemia which is the most common form of hyperbilirubinemia.

Two contraindications published in American Academy of Pediatrics (AAP) Guidelines were added to the Indications for Use of the subject device. Neither of these raise any new safety of effectiveness questions.

Comment 2

All the materials used for patient contact which includes Swaddle, Disposable Cover, Dual Fiber Optic Panels, and Single Fiber Optic Panel have been passed the biocompatibility test (ISO 10993-1). There is no publicly-available information of predicate device.

Comment 3

The targeted population of predicate device is neonates which includes pre-term neonates and term neonates. The Neonatal Phototherapy System, Model: KANGALITE is more specific to describe the targeted population with gestational age and weight limit which is Neonates: gestational age ≥ 38 weeks and weigh within 2500-4500 grams, that is excluded pre-term neonates. The risk of the targeted population of subject device is a subset of the predicate, and it does not raise new safety and effectiveness questions.

Comment 4

Neonatal Phototherapy System, Model: KANGALITE does not include the design of overhead phototherapy treatment. Comparison to be made only with the Fiber Optic Panel treatment mode for Neonatal Phototherapy System, Model: KANGALITE to that of the predicate product. The difference does not raise any new safety and effectiveness questions as the predicate also includes the mode of fiber optic panel.

Comment 5

The predicate device uses disposable cover onto the panel to wrap-around the baby. It does not include the swaddle component. The Swaddle in the subject device, Neonatal Phototherapy System, Model: KANGALITE, is used to enclose the Fiber Optic Panel and block the treatment blue light from leakage. The Table Mounting Clip, Shoulder Strap do not impact the performance of the device. These difference does not raise any new or different questions of safety or effectiveness for the subject device, Neonatal Phototherapy System, Model: KANGALITE.

Comment 6

Both devices use the same principle - blue light, peak emission in the wavelength range 430-490 nm and irradiance >30 μW/cm²/nm - recommended by the AAP for intensive phototherapy treatment. The subject device, Neonatal Phototherapy System, Model: KANGALITE, meets the recommend range and has performed and passed the bench test for the light peak emission, irradiance. The test demonstrates that the Neonatal Phototherapy System, Model: KANGALITE is as safe and effective as the predicate device.

Comment 7

KANGLITE has a longer expected LED lifetime than the predicate device. The performance test has conducted which can demonstrate the specification of KANGALITE LED lifetime. The different does not raise any new safety and effectiveness questions.

Comment 8

The connection mechanism of the subject device and predicate device is different. A “click” sound will appear when the subject device bundle end direct insert to the Light Source, operator can ensure the bundle has been inserted properly by the “click” sound. This difference does not raise new or different questions of safety or effectiveness for the subject device.

Comment 9

The dimensions and weight of the Light box are similar between the subject device and the predicate device. This difference does not raise new or different questions of safety or effectiveness for the subject device.

Comment 10

There are no relevant differences in the therapy, except that the subject device, Neonatal Phototherapy System, Model: KANGALITE, enables to cover a larger portion of the body surface of the infant. The APP recommends covering as much as possible the body surface of the infant for

phototherapy treatment. Therefore, the difference does not raise new or different questions of safety or effectiveness.

Comment 11

The Swaddle of the subject device is made by 100% cotton, it complies with the ISO 10993-5:2009 Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity and ISO 10993- 10:2010 Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization. The materials tested were found to be non-cytotoxic, non-sensitizers, and non-irritants. This difference does not raise any new or different questions of safety or effectiveness for the subject device.

Comment 12

The Neonatal Phototherapy System, Model: KANGALITE has undergone biocompatibility testing for the patient contact components (Swaddle, Disposable Cover and Fiber Optic Panel) in compliance with the ISO 10993 standards. The bench tests for the subject device has performed and the test results demonstrate that the design of subject device meet the specification which showing on the labeling and verified the safety and/or effectiveness for the subject device.

Comment 13

The subject and predicate device are intended for home and hospital use. The Neonatal Phototherapy System, Model: KANGALITE is fulfilled the requirement of IEC 60601-1-11:2015 General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home health care environment, which is verified the safety and/or effectiveness for home use.

Comment 14

Consider the Neonatal Phototherapy System, Model: KANGALITE can be used in the home environment, the design of the Light Source is fulfilled IP22 requirement. The test conducted against falling water when tilted up to 15 degrees and against solid foreign objects of 50 mm diameter and greater which is fulfilled the requirement in according with IEC 60601-1-11 for home use. While the waterproof level of the Light box of predicate device is IPX0 which is no special protection from water. It does not raise new safety and effectiveness questions.

8. Non-clinical Tests

The following bench testing was performed and reviewed to support the substantial equivalence of the subject device, Neonatal Phototherapy System, Model: KANGALITE, results of testing were acceptable.

1. The expected duration of treatment with the KANGALITE is 48-72 hours. Using ISO

10993-1:2009, this Nature of Body Contact is categorized as "Surface Device / Skin" with a "B - Prolonged (> 24 h to 30 days)" Contact Duration for all patient-contact materials. Therefore, the following biocompatibility tests were conducted on the disposable covers and Swaddle; the KANGALITE disposable covers and Swaddle passed all of these tests:

- Cytotoxicity (ISO 10993-5:2009)
- Sensitization (ISO 10993-10:2010)
- Sensitization (ISO 10993-10:2010)
- Skin Irritation (ISO 10993-10:2010)
- Skin Irritation (ISO 10993-10:2010)

2. Electrical safety and EMC testing were conducted to establish conformance with the following voluntary, FDA-recognized standards:

- ANSI/AAMI ES60601-1:2005/(R)2012 and A1:2012 C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text) Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)
- 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 Edition 2.1 2016-04 Medical electrical equipment - Part 2-50: Particular requirements for the basic safety and essential performance of infant phototherapy equipment [Including: Amendment 1 (2016)]
- IEC 60601-1-11 Edition 2.0 2015-01 Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment

Reprocessing and Cleaning/Disinfection

The subject device and accessories were assessed in accordance with the FDA guidance as applicable: Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling: Guidance for Industry and Food and Drug Administration Staff, 2015.

Human Factors Study:

The human factors/usability test protocol and report inclusive of human factors validation data was performed in accordance with the FDA guidance "Applying human factors and usability engineering to medical devices"

and IEC 62366.

Risk Analysis:
Risk Analysis: ISO 14971:2019 Medical Devices-Application of risk management to medical devices

9. Clinical study

No clinical study is included in this submission

10. Conclusions:

Based on the performance testing, comparison, and risk analysis in this submission, the subject device Neonatal Phototherapy System, Model: KANGALITE is substantially equivalent to the predicate device K070180.