September 5, 2019

Little Sparrows Technologies, Inc.
Erica Kontson
Product Engineer
176 Mystic Valley Parkway
Winchester, Massachusetts 01890

Re: K190899
Trade/Device Name: bili-hut™
Regulation Number: 21 CFR 880.5700
Regulation Name: Neonatal Phototherapy Unit
Regulatory Class: Class II
Product Code: LBI
Dated: August 7, 2019
Received: August 8, 2019

Dear Erica Kontson:

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 Alan Stevens
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190899

Device Name
bili-hut™

Indications for Use *(Describe)*
The bili-hut™ provides phototherapy for the treatment of neonatal hyperbilirubinemia, commonly known as neonatal jaundice, during the newborn period in the clinical or home setting.

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

K190899

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

I. SUBMITTER

Little Sparrows Technologies, Inc.
176 Mystic Valley Parkway
Winchester, MA 01890 USA

Phone: (781) 725-2460

Contact Person: Erica Kontson
Phone: (781) 725-2460
Email: erica@littlesparrowstech.com
Date Summary Prepared: August 21, 2019

II. DEVICE

Trade or Proprietary Name:	**bili-hut™**
Common or Usual Name:	Infant phototherapy (blue light) medical device
Classification Name:	Neonatal phototherapy unit
Regulatory Class:	II
Product Code:	LBI
Regulation Number:	21 CFR 880.5700

III. PREDICATE DEVICE

510(k) Number:	K974830
Device Name and Model:	Ultra Bili Light™ Model 2000
Manufacturer Name:	Physician Engineering Products, Inc.
Regulation Number:	21 CFR 880.5700
Classification Name:	Neonatal phototherapy unit

IV. DEVICE DESCRIPTION

The **bili-hut™** is a modular, portable blue LED-based phototherapy device intended to treat neonatal hyperbilirubinemia, commonly known as infant jaundice.

The expected duration of treatment with the **bili-hut™** is 48-72 hours, including interruptions for feeding, changing diapers and routine infant care as needed. The duration and method of treatment for each patient is decided by the prescribing clinician based on the baby's bilirubin levels and any other relevant medical history.

The **bili-hut™** is used in the clinical or home setting.

Components and Optional Accessory: The **bili-hut™** consists of the following components:

1. Assembled hut
    a. Shell (includes the light source – blue LEDs)
    b. Base mattress
    c. Base
2. Nest components
    a. Nest
    b. Nest liner (intended patient contact)
    c. Nest mattress
    d. Nest mattress cover (intended patient contact)
3. Power supply

The **bili-hut™** has an optional accessory, the **perch**, which is a bassinet stand insert providing a treatment surface for the device in the hospital setting with the use of a hospital grade bassinet stand.

Features: The **bili-hut™** features a timer which tracks the total use of the blue LED treatment lights in hours. The timer does NOT track individual patient treatment times. The device also has an Environment High Temperature Warning (EHTW) which is triggered at 43°C (109.4°F) when the **bili-hut™** is placed in extremely high environmental temperature conditions. This feature turns off the blue treatment lights and alerts the user with a yellow indicator light on top of the shell.

Principle of Operation: Phototherapy is the principle of operation for the **bili-hut™**; the neonate is treated with blue light to decrease bilirubin blood levels by breaking down the bilirubin so it can pass out of the neonate's body. The **bili-hut™** has one mode of operation; it is selected by the user with the on/off switch. The device is powered by a 12 V medical grade power supply and utilizes an LED light array to deliver therapeutic treatment. The average irradiance exceeds the American Academy of Pediatrics (AAP) standards[1] for high intensity phototherapy: an irradiance greater than 30 $\mu W/cm^2/nm$. Similarly, the **bili-hut™** output average peak wavelength is consistent with the AAP standard wavelength 430-490 nm. Neither the output intensity nor the output wavelength are adjustable for the **bili-hut™**. Like other neonatal phototherapy devices, the blue phototherapy light from the **bili-hut™** converts the yellow bilirubin pigment into a form that can naturally pass through the body, thus lowering the level of bilirubin in the infant's body.

Materials: The **bili-hut™** is comprised of fabric-based, plastic, metal and electronic materials. Fabric materials include nylon, vinyl, polyester, cotton, polyethylene foam,

[1] American Academy of Pediatrics Subcommittee on Hyperbilirubinemia. Clinical Practice Guideline. Management of Hyperbilirubinemia in the Newborn Infant 35 or More Weeks of Gestation. Pediatrics 2004;114:297-316.

hook & loop (Velcro) and polypropylene nonwovens. Plastic materials include polycarbonate, thermal polyurethane, nylon resin, high density polyethylene (HDPE) and styrene-butadiene rubber (SBR). Metal materials include aluminum, metalized polyethylene terephthalate (PET), zinc-plated steel and nickel. Electronic materials include components from printed circuit boards (PCBs), light emitting diodes (LED) and the power supply. The intended patient contact **bili-hut™** components (disposable nest cover and disposable nest mattress liner) are comprised of polypropylene nonwovens, which are expected to be in contact with the patient throughout the duration of treatment (decided upon the prescribing clinician's discretion, usually 48-72 hrs).

Patient Contact Component	Material
nest liner	polypropylene nonwoven
nest mattress cover	polypropylene nonwoven

The **bili-hut™** is not to be used to treat a patient who is in an incubator or under a radiant warmer because it was not designed to be used with these two types of medical devices. Furthermore, Little Sparrows Technologies recommends that the **bili-hut™** be used for patients with a birthweight of more than 2500 grams (5.5 pounds) and with a gestational age of greater than or equal to 35 weeks. However, the prescribing clinician defines the need for phototherapy with each patient.

Performance Specifications: The following are key performance specifications and features of the **bili-hut™**:

- Output peak wavelength:463 nm
- Average irradiance: 45 μW/cm^2/nm
- Effective treatment area: 170 in^2 (1097 cm^2)
- Peak irradiance: 58 μW/cm^2/nm
- Cleanable with a hospital grade disinfectant
- Environment High Temperature Warning indicator light associated with an automatic shutoff circuit to indicate when the device is used in an environment with a temperature that is too high

V. INDICATIONS FOR USE

Indications for Use: The **bili-hut™** provides phototherapy for the treatment of neonatal hyperbilirubinemia, commonly known as neonatal jaundice, during the newborn period in the clinical or home setting.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The Ultra Bili Light™ Model 2000 (K974830) and **bili-hut™** are substantially equivalent as summarized in **Table 5-1**.

Table 5-1: Comparison Table, Ultra Bili Light™ Model 2000 vs. bili-hut™

Device	**bili-hut™ (K190899)**	**Ultra Bili Light™ Model 2000 (K974830)**	**Discussion**
DEVICE USE & OTHER GENERAL CHARACTERISTICS			
Tradename	**bili-hut™**	Ultra Bili Light™ Model 2000	N/A
510(k) Number	K190899	K974830	N/A
Manufacturer	Little Sparrows Technologies, Inc.	Physician Engineering Products, Inc.	N/A
Regulation Name	Neonatal phototherapy unit	Neonatal phototherapy unit	Same
Intended Use	For treatment of neonatal hyperbilirubinemia	For treatment of neonatal hyperbilirubinemia	Same
Indications for Use	The **bili-hut™** provides phototherapy for the treatment of neonatal hyperbilirubinemia, commonly known as neonatal jaundice, during the newborn period in the clinical or home setting.	The intended use of the portable Ultra Bili Light™ model 2000 is to provide Home Phototherapy treatment for Neonatal Hyperbilirubinemia.	Similar; both devices are indicated for treatment of neonatal hyper-bilirubinemia in the hospital or home setting using blue light phototherapy. See SE discussion #1.
Environment of Use	Clinical or home setting	Clinical or home setting	Same See SE discussion #1.
Use Intent	Multi-patient with disposables	Multi-patient with disposables	Same
Prescription Use / Over-The-Counter Use	Prescription Use	Prescription Use	Same

Device	bili-hut™ (K190899)	Ultra Bili Light™ Model 2000 (K974830)	Discussion
Disposable / Reusable	Reusable device with disposable covers (nest mattress cover & nest liner) and disposable mattress	Reusable device with disposable mattress and cover	Same; **bili-hut™** includes disposable covers for the patient-contact surfaces (the nest mattress cover & nest liner)
TECHNOLOGICAL CHARACTERISTICS			
Principle of Operation	Phototherapy: neonate is treated with blue light to decrease bilirubin blood levels by breaking down the bilirubin so it can pass out of the neonate's body	Phototherapy: neonate is treated with blue light to decrease bilirubin blood levels by breaking down the bilirubin so it can pass out of the neonate's body	Similar
Energy Source	Blue light LED	Blue light fluorescent	Different; both devices deliver therapeutic irradiance at an intensity average above 30 $\mu W/cm^2/nm$. The use of LED treatment lights vs. fluorescent lights does not raise new questions of safety or effectiveness. See SE discussion #2.
Light Source Wavelength	430-490 nm	430-500 nm	Similar; the **bili-hut™** light source is within the range recommended by the AAP (430-490 nm).

Device	bili-hut™ (K190899)	Ultra Bili Light™ Model 2000 (K974830)	Discussion
Average irradiance of intended treatment area	45 µW/cm^2/nm	60 µW/cm^2/nm	Similar; both devices deliver therapeutic irradiance at an intensity average above 30 µW/cm^2/nm.
Intended Patient-contact Material(s)	Nest mattress cover (single-use) covering nest mattress: Polypropylene Nonwoven Nest liner (single-use) covering nest: Polypropylene Nonwoven	Nonwoven spunlaced polyester pad on top of a vinyl covered foam cushion	Similar; both devices use polyester material and a nonwoven material as the intended patient-contact material. The **bili-hut™** nest mattress cover and nest liner materials were tested for biocompatibility. Although not an intended patient-contact material, the **bili-hut™** nest mattress material was also tested for biocompatibility.
FEATURES			
Dimensions	16 in W (40.6 cm) 25 in L (63.5 cm) 12 in H (30.5 cm)	22.8 in W (58 cm) 18.1 in L (46 cm) 18.1 in H (46 cm)	Similar; both devices are built to fit into a standard crib or hospital grade bassinet.
Weight	14 lbs (6.3kg) with the perch accessory and 8 lbs (3.6kg) without the perch accessory	14 lb (6.5 kg)	Similar; both devices are lightweight enough for the caregiver to easily carry and maneuver.

Device	bili-hut™ (K190899)	Ultra Bili Light™ Model 2000 (K974830)	Discussion
SAFETY			
Mechanical Safety	Four fastening mechanisms ensure the device is redundantly secured. The nest holds the newborn in place and prevents any falling items from causing the shell to collapse onto the newborn.	Built-in tray holds newborn. Fits inside crib, not bassinet. *BabyFace Shield* or eye patches protect newborns' eyes. Two Sidewings are locked into place with a Crosspanel to hold the top of the suit-case up.	Similar; both devices contain redundant fastening mechanisms in the event of fastening mechanism failure.
Thermal Safety	Device material in contact with the newborn is non-conductive, fabric-covered foam. LEDs are out of reach of newborn (~6 in, or ~15 cm, from newborn's chest to interior of shell) and they are placed behind a plastic component. The **bili-hut™** has an over temperature shutoff circuit that detects the temperature of the interior surface of the **bili-hut™** shell when it is higher than 43°C (109.4°F) as per Clause 201.11.1.2.2 of IEC 60601-2-50 (2009). If the circuit is triggered, it turns off the treatment lights. Also, a yellow indicator light appears on the top of the shell; it is referred to as the "Environment High Temperature Warning."	Heating pad under newborn is turned on if Baby Tray is below 75°F (24°C). Thermal protection circuit sounds a beeper, flashes the treatment lights and eventually turns off the treatment lights if Baby Tray is over 98°F (36.7°C).	Different; both devices contain measures to protect the infant from overheating in the event that the environment is too warm. The **bili-hut™** does not include a heating feature. See SE discussion #3.

Device	bili-hut™ (K190899)	Ultra Bili Light™ Model 2000 (K974830)	Discussion
Visible Light Radiation Safety	Newborn's eyes will be protected from harmful blue light through the use of separate eye protection (i.e. user-selected protective eye covers or goggles).	The *BabyFace Shield* (K882291) or eye patches protect the newborn's eyes from harmful blue light.	Similar; both devices require external patient eye protection.
Ultraviolet Light Radiation Safety	LED light source emits no UV light.	UV-blocking plastic sheet (UV Lens) covers fluorescent bulbs.	Different; **bili-hut™** emits no UV light whereas predicate device filters out the UV light. See SE discussion #2.
HUMAN FACTORS			
Controls and indicators	• On-off switch • Hour meter (Timer tracks total hours of LED use) • High temperature indicator light (Environment High Temperature Warning)	• On-off switch • Hour meter • Low/high temperature indicator lights • 2,000-hour bulb change indicator	Similar; with the **bili-hut™** use of LEDs, a "bulb change" indicator is not applicable.
Compatibility with environment	Used inside crib or on hospital cart with the perch (hospital bassinet stand insert). Also can be used on a table with approximate dimensions of 2 ft x 4 ft in the home setting.	Used inside crib or on specialized hospital cart	Similar; the **bili-hut™** is able to be used on various surfaces in the hospital and home settings.

Device	bili-hut™ (K190899)	Ultra Bili Light™ Model 2000 (K974830)	Discussion
COMPLIANCE WITH STANDARDS			
Electrical Safety Testing	• AAMI ES60601-1:2005 + A1, • IEC 60601-1-6 Edition 3.1 2013, • IEC 62366-1 Ed. 1.0 2015, • IEC 60601-1-11 Edition 2.0 2015; and • IEC 60601-2-50 Edition 2.1 2016	There is no publicly-available information stating the predicate device underwent electrical safety testing in compliance with the 60601-1 standard of the time. Furthermore, the 60601-2-50 standard specific for infant phototherapy equipment did not yet exist at the time the predicate device's 510(k) was submitted.	Different; the predicate device likely underwent some type of electrical safety testing and the **bili-hut™** underwent electrical safety testing to current standards. See SE discussion #4.
Electromagnetic Compatibility (EMC) Testing	IEC 60601-1-2 Edition 4.0 2014 - Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests	There is no publicly-available information stating the predicate device underwent electrical safety testing in compliance with 60601-1-2 of the time (1st edition). Furthermore, the 60601-2-50 standard specific for infant phototherapy equipment did not yet exist at the time the predicate device's 510(k) was submitted.	Different; the predicate device likely underwent some type of EMC testing and the **bili-hut™** underwent EMC testing to current standards. See SE discussion #4.

Device	bili-hut™ (K190899)	Ultra Bili Light™ Model 2000 (K974830)	Discussion
Biocompatibility Testing	• Cytotoxicity (ISO 10993-5:2009), MTT Method, MEM with 10% FBS Extract • Sensitization (ISO 10993-10:2010), Guinea Pig Maximization Test, 0.9% Sodium Chloride Injection Extract • Sensitization (ISO 10993-10:2010), Guinea Pig Maximization Test, Cottonseed Oil Extract • Skin Irritation (ISO 10993-10:2010), intracutaneous injection, 0.9% Sodium Chloride Injection Extract • Skin Irritation (ISO 10993-10:2010), intracutaneous injection, Cottonseed Oil Extract	LST could not locate any publicly-available information stating the predicate device underwent biocompatibility testing to confirm the patient contact materials were in compliance with the ISO 10993 standards of the time. However, it is reasonable to assume biocompatible materials were used.	Different; the Sponsor assumes that the predicate device is constructed of biocompatible materials. See SE discussion #4.

SE Discussion #1 (Indications for Use / Environment of Use):

Both the **bili-hut™** and Ultra Bili Light™ Model 2000 indications for use include treatment of neonatal hyperbilirubinemia. The **bili-hut™** Indications for Use include treatment in the clinical **and** the home setting. The Ultra Bili Light™ Model 2000 Indications for Use, as per K974830's clearance letter states: "The intended use of the portable Ultra Bili Light model 2000 is to provide Home Phototherapy treatment for Neonatal Hyperbilirubinemia." Thus, upon clearance, it was used only for treatment in the home environment. However, Physician Engineered Products, Inc. used the Ultra Bili Light™ Model 2000 as the predicate device for their Bright Embrace Model SBL60 and the 510(k) summary for the Bright Embrace Model SBL60 (K110550) states the Ultra Bili Light™ Model 2000 "sites of use" include both

the clinical and home-use settings. This difference does not raise any new or different questions of safety or effectiveness for the subject device.

SE Discussion #2 (Energy Source: Blue Light LED vs. Blue Light Fluorescent):

The **bili-hut™** uses blue LED treatment lights and the Ultra Bili Light™ Model 2000 uses a blue fluorescent light source. Both provide an average irradiance greater than 30 μW/cm^2/nm. The use of LED lights does not raise any new safety or efficacy concerns compared to the use of fluorescent lights.

SE Discussion #3 (Thermal Safety):

The Ultra Bili Light™ Model 2000 includes a heating pad that is turned on if the Baby Tray is below 75°F (24°C). The **bili-hut™** does not include a warming feature because the assembled hut was designed to minimize convective heat loss from the newborn during treatment. The **bili-hut™** assembled hut is not designed to act as a warmer, but it is designed to contain the heat produced by the newborn as if the newborn were swaddled.

Both devices contain measures to protect the infant from overheating. However, the **bili-hut™** cut-off temperature, 43°C (109.4°F), is higher than the Ultra Bili Light™ Model 2000 cut-off temperature, 98°F (36.7°C). The **bili-hut™** over-temperature (Environment High Temperature Warning) was designed to be compliant with clause 201.11.1.2.2 of IEC 60601-2-50 (2009). The first edition of IEC 60601-2-50 had not yet been published at the time of the predicate device's submission so that most likely explains the difference from the predicate device's temperature cut-off. This difference does not raise any new or different questions of safety or effectiveness for the subject device.

SE Discussion #4 (Electrical Safety Testing, Electromagnetic Compatibility (EMC) Testing) and Biocompatibility Testing):

The **bili-hut™** has undergone electrical safety testing and EMC testing to confirm compliance with current internationally-recognized standards, all of which are FDA-recognized. The **bili-hut™** has undergone biocompatibility testing for the patient contact components (nest liner and nest mattress cover) in compliance with the ISO 10993 standards. Refer to Section VII for further details about the electrical safety testing, EMC testing and biocompatibility testing. This difference does not raise any new or different questions of safety or effectiveness for the subject device.

VII. PERFORMANCE DATA – NON-CLINICAL TESTING

The expected duration of treatment with the **bili-hut™** is 48-72 hours. Using ISO 10993-1:2009, this Nature of Body Contact is categorized as "Surface Device / Skin" with a "B – Prolonged (> 24hrs to 30 days)" Contact Duration for all patient-contact materials. Therefore, the following biocompatibility tests were conducted on the disposable covers and nest mattress; the **bili-hut™** disposable covers and nest

mattress passed all of these tests:

- Cytotoxicity (ISO 10993-5:2009), MTT Method, MEM with 10% FBS Extract;
- Sensitization (ISO 10993-10:2010), Guinea Pig Maximization Test, 0.9% Sodium Chloride Injection Extract;
- Sensitization (ISO 10993-10:2010), Guinea Pig Maximization Test, Cottonseed Oil Extract;
- Skin Irritation (ISO 10993-10:2010), intracutaneous injection, 0.9% Sodium Chloride Injection Extract; and
- Skin Irritation (ISO 10993-10:2010), intracutaneous injection, Cottonseed Oil Extract.

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

- FDA Recognition # 19-4, AAMI ES60601-1:2005 + A1 - Medical electrical equipment - Part 1: General requirements for basic safety and essential performance,
- FDA Recognition # 5-89, IEC 60601-1-6 Edition 3.1 2013 - Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability,
- FDA Recognition # 5-114, IEC 62366-1 Ed. 1.0 2015 - Medical devices - Part 1: Application of usability engineering to medical devices,
- FDA Recognition # 19-14, IEC 60601-1-11 Edition 2.0 2015 - 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,
- FDA Recognition # 6-387, IEC 60601-2-50 Edition 2.1 2016 - Medical electrical equipment - Part 2-50: Particular requirements for the basic safety and essential performance of infant phototherapy equipment [Including: Amendment 1 (2016)]; and
- FDA Recognition # 19-8, IEC 60601-1-2 Edition 4.0 2014 - Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests.

Bench performance tests including testing for device power, electrical safety, performance of indicators, LED performance, system irradiance, system light intensity, accelerated lifetime and human factors/usability were completed to verify that the **bili-hut™** met its device requirements and specifications and to support the substantial equivalence of the **bili-hut™** to the predicate device Ultra Bili Light™ Model 2000.

VIII. PERFORMANCE DATA – CLINICAL TESTING

No clinical data were submitted to support the substantial equivalence of the **bili-hut™** to the predicate device Ultra Bili Light™ Model 2000.

IX. CONCLUSIONS

Based on device characteristics compared in **Table 5-1** and the results of Little Sparrows Technologies' performance testing demonstrate that the **bili-hut™** is substantially equivalent to the predicate device Ultra Bili Light™ Model 2000.