May 28, 2021

Bistos Co., Ltd.
℅ Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Drive,
Suite 510k
Saint Paul, Minnesota 55114

Re: K210289
Trade/Device Name: Infant Phototherapy Equipment
Regulation Number: 21 CFR 880.5700
Regulation Name: Neonatal phototherapy unit
Regulatory Class: Class II
Product Code: LBI
Dated: April 9, 2021
Received: April 29, 2021

Dear Prithul Bom:

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)*

K210289

Device Name

BiliTouch™ (model name: Motif Phototherapy Blanket); and
Infant Phototherapy Equipment (model name: BT-450)

Indications for Use *(Describe)*

The BiliTouch™, model Motif Phototherapy Blanket and Infant Phototherapy Equipment, model BT-450 are indicated for use to treatment of infants diagnosed with hyperbilirubinemia, commonly known as neonatal jaundice, which can cause a yellow discoloration of the skin and the whites of the eyes. The devices can be used in a hospital or at home.

The device is designed to use for patient population described in the infant, who is age up to 3 months and weight less than 10 kg.

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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Traditional 510(k) Summary

This summary of 510(k) information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date 510k summary prepared: April 9, 2021

I. SUBMITTER

Submitter's Name	Bistos Co., Ltd.
Submitter's Address	7th Fl. A Bldg., Woolim Lions Valley 5-cha, 302, Galmachi-ro, Jungwon-gu, Seongnam-si, Gyeonggi-do, Korea (Zip. 13201)
Submitter's Telephone	+82 (31) 7500340
Contact person	Daeeun Kim (dekim@bistos.co.kr) / RA

II. DEVICE

Common Name	Neonatal phototherapy unit
Trade/proprietary Name	Infant phototherapy equipment, model BT-450 BiliTouch™, model Motif Phototherapy Blanket
Regulation Name	Unit, Neonatal Phototherapy
Regulation Number	21 CFR 880.5700
Product Code	LBI
Regulatory Class	Class II
Regulation Medical Specialty/510(k) review Panel	General Hospital

III. PREDICATE DEVICE

Primary Predicate device	BiliBee K072097 Illumination Technologies, LLC

IV. DEVICE DESCRIPTION

Infant phototherapy equipment is a portable phototherapy light system delivers a narrow band of high-intensity blue light via blue light-emitting diodes (LEDs) to provide treatment for neonatal unconjugated hyperbilirubinemia. The device is comprised of a control box and pad including a disposable pad cover, rechargeable battery and AC/DC power supply. The pad is designed to provide phototherapy treatment from underneath the baby.

Infant phototherapy equipment provides blue LEDs to achieve intensities by two-level with emitting light from blue LEDs (bandwidth 400 – 550 nm used).

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 the device can be applied at home or in a hospital.

V. INDICATIONS FOR USE:

The BiliTouch™, model Motif Phototherapy Blanket and Infant Phototherapy Equipment, model BT-450 are indicated for use to treatment of infants diagnosed with hyperbilirubinemia, commonly known as neonatal jaundice, which can cause a yellow discoloration of the skin and the whites of the eyes. The devices can be used in a hospital or at home.

The device is designed to use for patient population described in the infant, who is age up to 3 months and weight less than 10 kg.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The intended use, design and functional characteristics between the Infant phototherapy equipment and the predicate device are substantially equivalent. The subject device and predicate device is intended to be used for the treatment of infants diagnosed with hyperbilirubinemia by delivering light to degrade bilirubin on the same operating principle.

Summary table of technological characteristics of the device compared to the predicate device:

Device	K210289	K072097
Trade name	Infant phototherapy equipment, BiliTouch™	BiliBee
Model	BT-450,	

	Motif Phototherapy Blanket	
Manufacturer	Bistos Co., Ltd.	Illumination Technologies, LLC
Intended Use /Indications for Use	The BiliTouchTM, model Motif Phototherapy Blanket and Infant Phototherapy Equipment, model BT-450 are indicated for use to treatment of infants diagnosed with hyperbilirubinemia, commonly known as neonatal jaundice, which can cause a yellow discoloration of the skin and the whites of the eyes. The devices can be used in a hospital or at home. The device is designed to use for patient population described in the infant, who is age up to 3 months and weight less than 10 kg	The intended use of the BiliBee LED Phototherapy System is the treatment of infants diagnosed with hyperbilirubinemia, commonly known as neonatal jaundice, which can cause a yellow discoloration of the skin and the whites of the eyes.
Targeted population	Infant diagnosed with hyperbilirubinemia	Infant diagnosed with hyperbilirubinemia
Use environment	Home, Hospital	Home, Hospital
Type of device	blanket type device wrapping the patient	Free standing device underneath the patient
Visual Indicator	LCD	LCD
User control	1. Power on/off 2. Intensity level up and down 3. Run time setting - 30minutes increase - 30minutes decrease	Power on/off
Configuration	1. Control box which contains LCD display and Battery 2. Pad which consists of LEDs to emit light and is able to wrap around a patient 3. Pad cover 4. Adapter	1. AA battery pack 2. LED illuminator panel 3. Sheath 4. Adapter
Power	1. AC adapter: 100-240 Vac, 50/60Hz, 2.0A 2. Battery: 11.1V Li-ion Polymer 4000mA Charging time:	1. AC adapter: 2. Battery: Removable rechargeable 6 V battery(off-the-shelf AA battery)
Cover	Disposable pad cover, Which is made of white nonwoven spunbond	The disposable sheath consists of two pieces of synthetic woven fabric sewn together on 3 of 4 sides.
Use duration	Not limited, but the pad cover is intended to be replaced every 24 hours	Treatment is intended to be applied for 24 hours a day, and treatment time is expected to range from 3 days to 3 weeks.
Eye shield	Using is recommended.	None

Weight	1. Pad: 340 g 2. Control box: 370 g	1. Light panel < 0.5 lb.(227 g) 2. Battery pack < 1 lb. (454 g)
Dimensions	120 X 455 mm	4 X 8 inch (102 X 203 mm)
Type of light	Blue light LED	Flexible LED array emitting blue light
Lifetime of the lamp	3 years	Not available
Illuminated area	102 X 412 mm	102 X 152 mm
Wavelength	455~465 nm	@470mm
Light output	2 level - HIGH irradiance: 60±10 μW/cm²/nm - LOW irradiance: 30±10 μW/cm²/nm	1 level - 60 ±10 μ W/cm²/nm
Alarms	1. Information signal for low battery and Pad connection 2. Low priority alarm for high temperature	1. Audible low battery warning
Acoustic energy	43 ±1 dBA	Not available
Thermal safety	Surface of PAD ≤ 40 °C	There is no publicly-available information stating the predicate device conducted thermal safety testing in compliance with the 60601-2-50 standard as this specific standard for infant phototherapy equipment did not yet exist when the predicate device's 510(k) was submitted.
Operating Environmental condition	- Operating temperature: 15 °C to 30 °C (59 °F to 86 °F) - Operating humidity: 5 % to 85 % non-condensing - Atmospheric pressure: 70 kPa to 106 kPa	Not available
Transport and storage environmental condition	- Operating temperature: 15 °C to 30 °C (59 °F to 86 °F) - Operating humidity: 5 % to 85 % non-condensing - Atmospheric pressure: 70 kPa to 106 kPa	Not available
Electrical safety	IEC 60601-1 IEC 60601-1-8 IEC 60601-1-11 IEC 60601-2-50	There is no publicly-available information stating the predicate device conducted 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 when the predicate device's 510(k) was submitted.

Electromagnetic compatibility	IEC 60601-1-2	There is no publicly-available information stating the predicate device conducted electromagnetic compatibility testing in compliance with the 60601-1-2 standard of the time.
Photobiological safety	IEC 62471	There is no publicly-available information stating the predicate device conducted photobiological safety testing in compliance with the IEC 62471 standard of the time.
IP ratings	Control box: IP 21 Pad: IP 23 Power adapter: IP 22	There is no publicly-available information about the IP ratings.

VII. SUMMARY OF NON-CLINICAL TESTS

Infant phototherapy equipment complies with voluntary standards for biocompatibility (in vitro cytotoxicity, irritation and sensitization testing), electrical safety, EMC testing, home healthcare environment, alarm system and infant phototherapy equipment:

Biocompatibility:

The components, pad cover, which are in direct contact with the user are identical to the predicate device. Testing was conducted in accordance with FDA Recognition # 2-245, ISO 10993-5:2009, Biological Evaluation of Medical Devices-- Part 5: Tests for In Vitro Cytotoxicity and FDA Recognition # 2-174, ISO 10993-10:2010, Biological Evaluation of Medical Devices - Part 10: Tests for Irritation and Skin Sensitization.

Electrical Safety:

Testing was conducted in accordance with FDA Recognition # 19-4, AAMI ANSI ES60601-1:2005/(R)2012 and A1:2012, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD) and FDA Recognition # 19-14, IEC 60601-1-11:2015 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.

Electromagnetic Compatibility:

Testing was conducted in accordance with FDA Recognition # 19-8, IEC 60601-1-2:2014 Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements And Tests.

Alarm system:

Testing was conducted in accordance with FDA Recognition # 5-76, IEC 60601-1-8: 2006 + AMD1:2012 IEC 60601-1-8 – 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.

Infant phototherapy equipment:

Testing was conducted in accordance with FDA Recognition # 6-387, IEC 60601-2-50:

2009/AMD1:2016 – Part 2-50: Particular Requirements for the basic safety and essential performance of infant phototherapy equipment.

Software verification and validation testing as recommended in FDA's Guidance Document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." (May 11, 2005)

Bench performance tests including testing for battery-powered operating test, light intensity test and testing for temperature on the pad of the device and high temperature alarm were completed to verify that the infant phototherapy equipment demonstrate the specifications.

VIII. PERFORMANCE DATA : CLINICAL TESTING

No clinical data were submitted.

IX. CONCLUSIONS

Based on device characteristics compared in Substantial Equivalence Discussion (TAB. NO.11) and the results of electromagnetic and electric safety and performance testing demonstrate that the infant phototherapy equipment and BiliTouch™, model name BT-450 and Motif Phototherapy Blanket are as safe and effective as the predicate device, BiliBee, K072097.