January 15, 2026

Thera B Medical Products
% Amy Oakes
Founder & Principal Consultant
Acorn N Oakes LLC
333 N. Dobson Rd. Suite 5
Chandler, Arizona 85224

Re: K251308
Trade/Device Name: SnugLit(TM) Wearable Phototherapy System (SNGL-01-US)
Regulation Number: 21 CFR 880.5700
Regulation Name: Neonatal Phototherapy Unit
Regulatory Class: Class II
Product Code: LBI
Dated: December 17, 2025
Received: December 17, 2025

Dear Amy Oakes:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Colleen J. Lawrimore -S

Colleen Lawrimore, Ph.D.
For David Wolloscheck, Ph.D.
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K251308

Device Name
SnugLit(TM) Wearable Phototherapy System (SNGL-01-US)

Indications for Use *(Describe)*
The SnugLit(TM) Wearable Phototherapy System is intended for use in the treatment of infant hyperbilirubinemia, commonly known as neonatal jaundice. The device can be used in a hospital or at home, by a licensed medical practitioner or by a caregiver under the supervision of a licensed medical practitioner.

The device has been designed for use with infants of weights between 1.5 – 5.5 kg (approximately 3.5 -12 lbs) and lengths between 40.5 - 57.5 cm (approximately 16 - 23 inches).

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."

K251308 - 510(K) SUMMARY

As required by 21 CFR 807.92(c)

Applicant Contact Details:

Name:	Thera B Medical Products
Address:	325 E. Grand River Ave. Suite 332 East Lansing, MI 48823
Telephone:	810-338-7965
Contact:	Alexa Jones
Email:	alexa.jones@therabmedical.com

Correspondent Contact Details:

Name:	Acorn N Oakes LLC
Address:	333 N. Dobson Rd. Suite 5 Chandler, AZ 85224
Telephone:	480-304-2165
Contact:	Amy Oakes
Email:	acornnoakes@cox.net

Date Prepared:

January 15, 2026

Device Information:

Trade/Proprietary Name:	SnugLit(TM) Wearable Phototherapy System (SNGL-01-US)
Common Name:	Neonatal phototherapy unit
Regulation Name:	Neonatal phototherapy unit
Regulation Number:	880.5700
Product Code:	LBI

Predicate Device:

510(k) Number	Device Name	Manufacturer
K210289	BiliTouch (Motif Phototherapy Blanket)	Bistos Co., Ltd.

Device Description:

The SnugLit system is a phototherapy device that provides therapeutic blue light to infants using a Light Mat enclosed within a Disposable Swaddle. This system enables infants to receive phototherapy in a bassinet or while being held. The SnugLit is designed to deliver wrap-around phototherapy to infants while being swaddled.

The SnugLit is composed of a Light Mat, Controller, Disposable Swaddle, and Power Adapter.

Indications for Use:

The SnugLit(TM) Wearable Phototherapy System is intended for use in the treatment of infant hyperbilirubinemia, commonly known as neonatal jaundice. The device can be used in a hospital or at home, by a licensed medical practitioner or by a caregiver under the supervision of a licensed medical practitioner.

The device has been designed for use with infants of weights between 1.5 - 5.5 kg (approximately 3.5 -12 lbs) and lengths between 40.5 - 57.5 cm (approximately 16 - 23 inches).

Indications for Use Comparison:

The SnugLit Wearable Phototherapy System (SnugLit) and the BiliTouch, model Motif Phototherapy Blanket and Infant Phototherapy Equipment (BiliTouch) are both indicated for treatment of infants diagnosed with hyperbilirubinemia.

The BiliTouch specifies a maximum age for treatment of 3 months and a weight of less than 10 kg, while the SnugLit does not specify an age limit but addresses the physical characteristics of the infant under treatment including a lower and upper limit for weight of 1.5 – 5.5 kg and a length range of 40.5 – 57.5 cm.

Testing of the SnugLit device has been performed for the listed weight and length ranges.

Technological Comparison:

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

A summary comparison of the technological characteristics of the devices can be found in the table below.

Characteristic	K251308 (SnugLit)	K210289 (BiliTouch)	Substantial Equivalence Discussion
Trade Name	SnugLit Wearable Phototherapy System	Infant Phototherapy Equipment, BiliTouch	-
Model	SNGL-01-US	BT-450	-
Manufacturer	Thera B Medical Inc.	Bistos Co., Ltd	-

Characteristic	K251308 (SnugLit)	K210289 (BiliTouch)	Substantial Equivalence Discussion
Intended Use / Indications for Use	The SnugLit(TM) Wearable Phototherapy System is intended for use in the treatment of infant hyperbilirubinemia, commonly known as neonatal jaundice. The device can be used in a hospital or at home, by a licensed medical practitioner or by a caregiver under the supervision of a licensed medical practitioner. The device has been designed for use with infants of weights between 1.5 - 5.5 kg (approximately 3.5 -12 lbs) and lengths between 40.5 - 57.5 cm (approximately 16 - 23 inches).	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	Substantially Equivalent Both units are intended for treatment of hyperbilirubinemia under the care of a medical practitioner. The SnugLit device identifies a weight and length requirement for determining use range. When compared to the predicate the allowable weight (10kg vs 5.5kg) and the typical length of an infant at 3 months of age as identified in the predicate of 24 inches, the SnugLit device is designed for a similar use case patient.
Targeted Population	Infant diagnosed with hyperbilirubinemia	Infant diagnosed with hyperbilirubinemia	Identical
Use Environment	Home, Hospital	Home, Hospital	Identical
Type of Device	blanket type device wrapping the patient	blanket type device wrapping the patient	Identical
Visual Indicator	LCD	LCD	Identical
User Control	• Power on/off • Intensity level up and down • Run-time counter displaying accumulated ON-time in hh:mm:ss, up to 24 hours.	• Power on/off • Intensity level up and down • Run time setting-30minutes increase-30minutes decrease	Substantially equivalent The SnugLit provides more precise monitoring of treatment time.

Characteristic	K251308 (SnugLit)	K210289 (BiliTouch)	Substantial Equivalence Discussion
Configuration	• Control box which contains LCD display and Battery	• Control box which contains LCD display and Battery	Identical
	• Light Mat which consists of LEDs to emit light and is able to wrap around a patient	• Pad which consists of LEDs to emit light and is able to wrap around a patient	Identical
	• Disposable Swaddle	• Pad cover	Substantially equivalent The predicate "Pad cover" and the SnugLit "Disposable Swaddle" are both disposable covers. The SnugLit device has been tested for Biocompatibility and Light Irradiance and shown substantial equivalence to the predicate Pad Cover.
	• Power Adapter	• Power Adapter	Identical
Power	• AC adapter: 80-264 Vac, 47-63 Hz, 1.5A	• AC adapter: 100-240 Vac, 50/60Hz, 2.0A	Substantially equivalent. The overall electrical safety of the SnugLit device was tested in accordance with IEC 60601-1 and met the applicable requirements.

Characteristic	K251308 (SnugLit)	K210289 (BiliTouch)	Substantial Equivalence Discussion
	• Battery: 3.7V Lithium Polymer 3800mA • Charging time: 2-3 hours	• Battery: 11.1V Li-ion Polymer 4000mA • Charging time: Unknown	Substantially equivalent. The battery has been sized to specifically meet the electrical needs of the LED configuration for the SnugLit which does not affect the overall functional output of LED wavelength or intensity as confirmed via design validation testing. The overall electrical safety of the SnugLit device was tested in accordance with IEC 60601-1 and met the applicable requirements.
Cover	Disposable pad (swaddle), Which is made of Grey Microfin Dry (a grey Spunbond material) and 40D Nylon Mesh (light transmissable)	Disposable pad cover, Which is made of white nonwoven spunbond	Substantially equivalent Both items are disposable pad covers. The SnugLit swaddle complied with applicable requirements of ISO 10993 and has been confirmed to provide the appropriate light transmissibility to support the requirements for phototherapy via design validation testing.
Use Duration	Not limited. Disposable Swaddle to be replaced every 24 hours or if soiled	Not limited, but the pad cover is intended to be replaced every 24 hours	Identical

Characteristic	K251308 (SnugLit)	K210289 (BiliTouch)	Substantial Equivalence Discussion
Eye Shield	Not Required	Using is recommended	Substantially equivalent Both devices provide protection from excess exposure to potentially harmful blue light. The SnugLit device has built in mechanism for eye protection as confirmed via design validation testing.
Weight	• Light Mat: 700 g • Control box: 488 g	• Pad: 340 g • Control box: 370 g	Substantially equivalent The devices are intended to be used while holding an infant wrapped in the device. Based on the intended use statements, the combined weight of the maximum identified infant and the device combined is substantially equivalent with the SnugLit being potentially lighter at the upper end of the use case. SnugLit: 13.5 lbs Predicate: 13.65 lbs
Dimensions	463 x 402 mm	120 X 455 mm	Substantially equivalent The dimensions of the SnugLit are sized to maximize body surface area of treatment which has been identified as a critical criterion in treatment of hyperbilirubinemia by AAP.
Type of Light	Blue light LED	Blue light LED	Identical

Characteristic	K251308 (SnugLit)	K210289 (BiliTouch)	Substantial Equivalence Discussion
Use Life	Light Mat: 3 years Disposable Swaddle: 24 hours if not damaged or soiled Controller: 5 years, exclusive of battery Controller battery: 1 year Power Adapter: 3-5 years	3 years	Light Mat: Identical Disposable Swaddle: Identical Other Items: Substantially equivalent The use life of the other components of the predicate are unknown; however, specification of the use life provides additional clarity to the user for better management of overall system life.
Illuminated Area	1080 cm^2	102 x 412 mm (420 cm^2)	Substantially equivalent The dimensions of the SnugLit are sized to maximize body surface area of treatment which has been identified as a critical criterion in treatment of hyperbilirubinemia by AAP.
Wavelength	459-480 nm	455-465 nm	Substantially equivalent The AAP recommended wavelength range for phototherapy is 460-490 nm. Both devices fall within this recommended range.
Light Output	2 level -HIGH irradiance: 65 ±15 µW/cm²/nm-LOW irradiance: 40±10 µW/cm²/nm	2 level -HIGH irradiance: 60±10 µW/cm²/nm-LOW irradiance: 30±10 µW/cm²/nm	Substantially equivalent The SnugLit device LOW irradiance has been adjusted to 40 µW/cm²/nm. Which is designed to ensure the minimum irradiance meets the 30 µW/cm²/nm recommended by the AAP for phototherapy.

Characteristic	K251308 (SnugLit)	K210289 (BiliTouch)	Substantial Equivalence Discussion
Alarms	• Information signal for low battery, pad connection, ambient temperature high, therapy paused • Low priority alarm for malfunction, battery critically low, pad disconnection, 24h therapy • Medium priority alarm for high temperature	• Information signal for low battery and Pad connection • Low priority alarm for high temperature	Substantially equivalent Alarms are specific to each device function. SnugLit has identified additional alarms specific to its functional parameters providing additional information to the user.
Acoustic Energy	Alerts: Max 59 dB(A)	43 ±1 dBA	Substantially equivalent IEC 60601-1-8 specifies alert noise levels should be below 65 dB(A) for neonatal levels. Both devices meet this requirement as confirmed via testing.
Thermal Safety	Surface of PAD ≤ 40 °C	Surface of PAD ≤ 40°C	Identical
Operating Environment	Temperature: 15 °C to 30 °C (59 °F to 86 °F) Humidity: 5% to 85 % non-Condensing Atmospheric pressure: 70 kPa to 106 kPa	Temperature: 15 °C to 30 °C (59 °F to 86 °F) Humidity: 5 % to 85 % non-condensing Atmospheric pressure: 70 kPa to 106 kPa	Identical
Storage and Handling Environment	Temperature - 20 °C to 60 °C (-4 °F to 140 °F) Humidity 0% to 95% non-condensing Atmospheric Pressure 70 kPa to 106 kPa	Unknown	Substantially equivalent Storage and Handling of the SnugLit has been designed to withstand the full range of anticipated transport conditions per ASTM D4169
Electrical Safety	IEC 60601-1 IEC 60601-1-8 IEC 60601-1-11 IEC 60601-2-50	IEC 60601-1 IEC 60601-1-8 IEC 60601-1-11 IEC 60601-2-50	Identical

Characteristic	K251308 (SnugLit)	K210289 (BiliTouch)	Substantial Equivalence Discussion
IP Rating	Light Mat: IP25 Controller: IP21 Power adapter: IP21	Pad: IP 23 Control box: IP 21 Power adapter: IP 22	Substantially Equivalent Both devices meet the requirements for solid protection (IP2x). Both units meet or exceed the liquid penetration requirements for indoor electronics (away from direct spray).
Electromagnetic Compatibility	IEC 60601-1-2	IEC 60601-1-2	Identical
Photobiological Safety	IEC 62471	IEC 62471	Identical

Function and Safety Testing:

Bench and Laboratory testing evaluating substantial equivalence to the predicate devices was performed including the following:

- Biocompatibility
    - ISO 10993-5 Cytotoxicity
    - ISO 10993-11 Skin Sensitization
    - ISO 10993-20 Irritation
- Light Characterization / Safety
    - IEC 60601-2-50 Basic Safety of Phototherapy
    - IEC 62471 Photobiological Safety
- Thermal Safety
    - IEC 60601-1 Electrical Safety
    - IEC 60601-2-50 Basic Safety of Phototherapy
    - IEC 62471 Photobiological Safety
    - IEC 60601-1-8 High Temperature Alarms
    - Thermal Cutoff – Hardware & Software Verification
    - Ambient Temperature Sensing
- Functional Performance
    - Swaddle Fit & Light Leakage
    - Life Cycle Testing
    - IEC 62304 Software Validation
- Electrical Safety / Battery performance
    - IEC 60601-1 – Electrical Safety
    - IEC 60601-1-2 – EMC
    - IEC 60601-1-11
    - 5G/WPT (FR1 Band)
- Usability
    - Applying Human Factors and Usability Engineering to Medical Devices Guidance for Industry and Food and Drug Administration Staff, issued February 2016

- Transit Testing ASTM D4169

No clinical tests were performed for this submission. Where patient representative elements were required for bench testing, a representative doll was used.

Thera B Medical concludes that the testing performed demonstrates substantial equivalence to the predicate devices.

Conclusion:

Based on the representative bench testing performed, Thera B concludes that the SnugLit Wearable Phototherapy System is substantially equivalent to the predicate device.