May 29, 2025

Gerium Medical, Ltd.
% Bosmat Friedman-Cox
Regulatory Consultant
ProMedoss, Inc.
6026 Beech Cove Ln.
Charlotte, North Carolina 28269

Re: K243372
Trade/Device Name: BiliWrap
Regulation Number: 21 CFR 880.5700
Regulation Name: Neonatal Phototherapy Unit
Regulatory Class: Class II
Product Code: LBI
Dated: May 26, 2025
Received: May 27, 2025

Dear Bosmat Friedman-Cox:

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,

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)*
K243372

Device Name
BiliWrap

Indications for Use *(Describe)*
The BiliWrap Phototherapy System is intended for use to treat infants who have been diagnosed with hyperbilirubinemia, commonly known as neonatal jaundice, which can cause a yellow discoloration of the skin and the whites of the eyes. The Phototherapy system can be used in a hospital or at home. The device is intended to be used in infants up to the age of 3 months, weighing 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

BiliWrap K243372

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

Date 510k summary prepared: May 28, 2025

I. SUBMITTER

510(k) Submitter: Gerium Medical Ltd.
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II. DEVICE

Device Common Name: Neonatal phototherapy device
Device trade or proprietary name: BiliWrap
Classification Name: Neonatal phototherapy unit
Classification Regulation: 21 CFR §880.5700
Device Classification: Class II
Device Product Code: LBI

III. PREDICATE DEVICE

Device trade name: BiliTouch™ (K210289)

IV. DEVICE DESCRIPTION

The BiliWrap Phototherapy System is a portable phototherapy light system that 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 and AC/DC power supply. The pad is designed to cover the torso and legs and provide phototherapy treatment on large surface area of the baby.

The BiliWrap Phototherapy System emits light in the spectrum of 450 to 475 nm, a spectrum known as effective to reduce bilirubin concertation in the body of infants. 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 BiliWrap Phototherapy System is intended for use to treat infants who have been diagnosed with hyperbilirubinemia, commonly known as neonatal jaundice, which can cause a yellow discoloration of the

skin and the whites of the eyes. The Phototherapy system can be used in a hospital or at home.
The device is intended to be used in infants up to the age of 3 months, weighing less than 10 kg.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

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

Characteristics	BiliWrap	BiliTouch ™	Comments
Indications for use	The BiliWrap Phototherapy System is intended for use to treat infants who have been diagnosed with hyperbilirubinemia, commonly known as neonatal jaundice, which can cause a yellow discoloration of the skin and the whites of the eyes. The Phototherapy system can be used in a hospital or at home. The device is intended to be used in infants up to the age of 3 months, weighing less than 10 kg	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.	Same
Population	Infant diagnosed with Hyperbilirubinemia, age up to 3 months, weighing less than 10 kg	Infant diagnosed with Hyperbilirubinemia, age up to 3 months, weighing less than 10 kg	Same
Use environment	Hospital, Home	Hospital, Home	Same
Principles of operation	Transmits blue led light in an effective spectrum and irradiance to the patient's body to reduce bilirubin level.	Transmits blue led light in an effective spectrum and irradiance to the patient's body to reduce bilirubin level.	Similar – BiliWrap has a larger treatment surface area

Characteristics	BiliWrap	BiliTouch ™	Comments
	The BiliWrap Ledpad covers the torso and legs in a 3D design	The BiliTouch wraps the patient from underneath the baby	
Configuration	The BiliWrap is composed of: 1. Control box which contains LCD display and power supply 2. Pad which consists of LEDs to emit light and is able to wrap around a patient 3. Pad cover (body shape Wrapper)	The BiliTouch ™ is composed of: 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	Similar
Operation control	1. Power on/off 2. Intensity level up and down 3. Run time setting : one displays the treatment duration (counting up) while the other shows the total remaining use hours on the device (counts down from either 3168 or 1584 hours).	1. Power on/off 2. Intensity level up and down 3. Run time setting - 30minutes increase - 30minutes decrease **Normal Mode -** The light pad is on and operates continuously	Similar; BiliWrap run time is preset
Light source	Blue Led light in an effective spectrum. emits light in the spectrum of 450 to 475 nm	Blue Led light in an effective spectrum. emits light in the spectrum of the 455 to 465 nm	Similar; BiliWrap spectrum is slightly wider but still in the AAP standard wavelength of 430-490 nm Reference: Subcommittee on Hyperbilirubinemia; Management of Hyperbilirubinemia in the Newborn Infant 35 or More Weeks of

Characteristics	BiliWrap	BiliTouch ™	Comments
			Gestation. Pediatrics July 2004; 114 (1): 297–316. 10.1542/peds.114.1.297
Power	Input: 100 -240VAC, 50/60 Hz Output13VdC / 2.3A 30W	1. Input: 100 to 240 V~, 50/60 Hz Output: 15 Vdc, 1.2 A 2. Battery: 11.1V Li-ion Polymer	Similar; both devices tested for EMC and electrical safety.
Power security	Double insulation class II	Class II	Same
Weight	1.Ledpad: 700g 2.Controller: 148g	1. Pad: 340 g 2. Control box: 370 g	Similar; BiliWrap has a larger treatment surface area and is therefore slightly heavier
Dimensions	1. Ledpad: 480mm x 455mm 2. Controller: 110mm x 80mm	1. Pad: 133mm x 459mm x 2. Controller: 85mm x 185mm	
Performance specifications	Type of blue light: Blue Led Light with peak Emission 450 nm – 475 nm Intensity: low: 30-40 uW/cm2/nm High: 40-50 uW/cm2/nm light emitting area: 1216 cm2	Type of blue light: Blue Led Light with peak Emission: 455 to 465 nm Intensity: LOW 30±10 μW/cm²/nm HIGH 60±10 μW/cm²/nm light emitting area: 420 cm2	Both devices emit within the AAP standard wavelength of 430-490 nm Reference: Subcommittee on Hyperbilirubinemia; Management of Hyperbilirubinemia in the Newborn Infant 35 or More Weeks of Gestation. Pediatrics July 2004; 114 (1): 297–316. 10.1542/peds.114.1.297
Materials or substances in contact with human tissues	The LEDpad is covered by a disposable nonwoven biocompatible Polypropylene, the nonwoven fabric covers	The lighting surface pad is covered by Disposable biocompatible pad cover, which is made of white nonwoven spunbond. The nonwoven cover covers the	Both devices tested per ISO 10993-1

Characteristics	BiliWrap	BiliTouch ™	Comments
	the patient's body and is in touch with the patient skin.	patient's body and is in touch with the patient skin.	
Duration of contact with the same human tissues	The patient will be in contact with the Ledpad wrapped with the nonwoven for a period time prescribed by the doctors. Wrapper is a single patient use, and should be disposed and replaced when soiled, and after each therapy session.	The patient is in contact with the BiliTouch pad wrapped with the nonwoven material for a period time prescribed by the doctors; the pad cover is intended to be replaced every 24 hours.	Same
EMC & Safety	IEC 60601-1-2 IEC 60601-1 IEC 60601-1-6 IEC 60601-1-11 IEC 60601-2-50 EC 62471	IEC 60601-1-2 IEC 60601-1 IEC 60601-1-8 IEC 60601-1-11 IEC 60601-2-50 EC 62471	Same; The BiliWrap was not tested per IEC 60601-1-8 as it does not include any audible alarms. The absence of audible alarms does not impact device performance, as it contains visual alarms instead.

Principle of Operation

The BiliTouch predicate has a uniform heat distribution; the blanket is partially open to allow the evaporation of the heat. Unlike the predicate, the BiliWrap does not cover the arms, however it is wrapped around the thighs, calves and ankles. The heat distribution on the BiliWrap is uniform, the LEDPad wrap is designed to allow for the evaporation of heat by breaking the wrap to 5 sections, and by leaving the arms uncovered.

Heat distribution and conformance to standards were evaluated in the various device performance testing and the results demonstrated that no new safety and effectiveness concerns are introduced due to the difference in wrap design.

Configuration

The BiliWrap operates with a continues timer display that indicated the duration of treatment since the device was turned on; the timer is paused when treatment is paused. The BiliTouch predicate has a Run time setting which enables to increase/decrease treatment duration by 30 min.

The BiliWrap was assessed for functional, electrical, and biocompatibility performance. No new safety and effectiveness concerns are introduced due to the difference counter/timer configuration.

Light and Power Source

The BiliWrap has a wider emission range than BiliTouch. Phototherapy with radiation of 430-490 nm wavelengths provides the most potent therapeutic effect for neonatal jaundice (Kato, et al., 2019) this range is also recommended by the AAP. The BiliWrap operates within the AAP recommended

effective spectrum and therefore, the difference in the light peak emission, does not raise new questions of safety or effectiveness.

The BiliWrap does not have the battery option and only operates on mains power. This minor difference does not raise new safety and effectiveness concerns. Both devices were tested for EMC and electrical safety.

Weight

The BiliWrap LEDPad is heavier than the BiliTouch pad however it also has a larger surface area and therefore the weight is distributed similarly.

Differences in weight due to the surface area of the subject device do not raise new questions of safety and effectiveness.

Performance Specifications

The spread of the BiliWrap LEDs on the flex board is designed to achieve recommended irradiance ≥ 30 µW/cm2/nm (Borden1, et al., 2018). Both devices use the same operating principle, i.e., blue light, peak emission in the wavelength range of 450-475nm and irradiance >30µW/cm²/nm – as recommended by the American Academy of Pediatrics for intensive phototherapy treatment (PEDIATRICS, 2004). The BiliTouch predicate is a blanket-type device, wrapping the patient, while the BiliWrap has a body shape LEDPad; due to its shape, the BiliWrap has a larger light emitting area. This does not introduce new safety and effectiveness concerns. Both devices use the same operating principle. Changes in the geometry of the wrap do not influence achieved radiation. There are no new questions of safety and effectiveness.

VII. SUMMARY OF NON-CLINICAL TESTS

BiliWrap complies with voluntary standards for biocompatibility, electrical safety, EMC testing, home healthcare environment and infant phototherapy equipment.

Testing was conducted in accordance with FDA Recognized Consensus Standards: Medical Devices

Standards	FDA Recognition number
Safety	
IEC 60601-1:2005, AMD1:2012, AMD2:2020 basic safety and essential performance for all medical electrical equipment	19-49
IEC 60601-1-2:2014/AMD1:2020 General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests	19-36
IEC 60601-1-6:2010, AMD1:2013, AMD2:2020	5-132

General requirements for basic safety and essential performance - Collateral standard: Usability	
IEC 60601-1-11:2015/AMD1:2020 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	19-38
IEC 60601-2-50:2020 Particular requirements for the basic safety and essential performance of infant phototherapy equipment	6-450
IEC 62304:2006+A1:2015 Software life cycle processes	13-79
IEC 62471:2006 Photobiological safety of lamps and lamp systems	12-249
Biocompatibility	
ISO 10993-1:2020 Evaluation and testing within a risk management process	2-296
Software verification and validation testing as recommended in FDA's Guidance Document "Content of Premarket Submissions for Device Software Functions" (June 14, 2023)	
Bench tests including durability test, light intensity test, temperature test and errors and alarm tests were completed to confirm that the BiliWrap functions as intended and pre the device's specifications.	

VIII. PERFORMANCE DATA: CLINICAL TESTING

No clinical data was required for this submission.

IX. CONCLUSIONS

The BiliWrap has the same intended use, technological characteristics, and principles of operation as the predicate. Any differences between the subject and predicate devices were evaluated through design verification and validation testing and comparative testing which demonstrated device performance and safety, and do not raise any new questions of safety and effectiveness.

Based on the information submitted in this 510(k), the BiliWrap is substantially equivalent to the currently marketed predicate BiliTouch™ cleared under K210289.