June 25, 2024

Laerdal Medical AS
% Daniel Dillon, M.S., Rac
Senior Regulatory Scientist
MED Institute
1330 Win Hentschel Blvd
West Lafayette, Indiana 47906

Re: K232111
Trade/Device Name: NeoBeat, NeoBeat Mini
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (Including Cardiotachometer And Rate Alarm)
Regulatory Class: Class II
Product Code: MWI
Dated: June 24, 2024
Received: June 24, 2024

Dear Daniel Dillon:

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.

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,

Jennifer W. Shih -S

Jennifer Kozen
Assistant Director
Division of Cardiac Electrophysiology,
Diagnostics and Monitoring Devices
Office of Cardiovascular 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)*
K232111

Device Name

NeoBeat and NeoBeat Mini

Indications for Use *(Describe)*

NeoBeat and NeoBeat Mini are indicated to continuously measure and display the heart rate of neonates using dry electrodes on the torso during transition, stabilization and/or resuscitation. The devices are intended to be used in healthcare facilities. NeoBeat is intended for use on newborns approximately 1.5-5 kg. NeoBeat Mini is intended for newborns approximately 0.5-2 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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510(k) Summary – K232111

NeoBeat Newborn Heart Rate Meter
21 CFR 870.2300
Date Prepared: June 20, 2024

Submitted By Mari Kaada, Corporate Quality and Regulatory Director
Laerdal Medical AS
Tanke Svilandsgate 30
P.O. Box 377
4002 Stavanger
Norway
T: (011) 47-51-51-16-30
Mari.Kaada@laerdal.com

Device Information

Trade Name:	NeoBeat/NeoBeat Mini
Common/Usual Name:	Heart Rate Meter
Classification Name:	Monitor, Physiological, Patient (Without Arrhythmia Detection or Alarms)
Regulation:	21 CFR 870.2300
Product Code:	MWI
Device Class:	Class II
Classification Panel:	Cardiovascular

Indications for Use

NeoBeat and NeoBeat Mini are indicated to continuously measure and display the heart rate of neonates using dry electrodes on the torso during transition, stabilization and/or resuscitation. The devices are intended to be used in healthcare facilities. NeoBeat is intended for use on newborns approximately 1.5-5 kg. The NeoBeat Mini is intended for newborns approximately 0.5-2 kg.

Predicate Device

The NeoBeat Newborn Heart Rate Meter is substantially equivalent to the predicate device, the Guangdong Biolight M800 Handheld Monitor (510(k) No. K131762, cleared June 6, 2014).

Device Description

The NeoBeat Newborn Heart Rate Meter is a battery-powered device placed on the torso of a newborn, indicated to measure the heart rate. NeoBeat does not store, display or output an ECG signal.

The device is placed around the torso of the neonate such that the ECG dry electrodes contact the neonate's skin. It can be oriented caudally or cranially. In normal operation, the LED display presents the heart rate in large numerals. The display can also present other information, such as signal quality and error codes. The device comes with a charging stand.

Substantial Equivalence

The NeoBeat Newborn Heart Rate Meter is substantially equivalent to the predicate device, the Guangdong Biolight M800 Handheld Monitor (510(k) No. K131762). The table below presents the similarities and differences between the two devices for substantial equivalence purposes, comparing the NeoBeat Newborn Heart Rate Meter to the heart rate indication and function of the Biolight M800.

The differences between the subject device and the predicate device do not raise any new issues of safety and effectiveness. Performance data are available to support substantial equivalence and were developed using acceptable scientific methods for evaluation.

	NeoBeat Newborn Heart Rate Meter (K232111)	**Biolight M800 Monitor (K131762)**
Intended Use		
Indication for use	NeoBeat and NeoBeat Mini are indicated to continuously measure and display the heart rate of neonates using dry electrodes on the torso during transition, stabilization and/or resuscitation. The devices are intended to be used in healthcare facilities. NeoBeat is intended for use on newborns approximately 1.5-5 kg. NeoBeat Mini is intended for newborns approximately 0.5-2 kg.	M800 handheld monitor is intended for continuously monitoring or spot checking of HR of adult, pediatric and neonatal patients in hospital, hospital type facilities as well as in the home care environment.
Patient population	Neonates	Adult, pediatric and neonates

	NeoBeat Newborn Heart Rate Meter (K232111)	Biolight M800 Monitor (K131762)
Users	Healthcare professionals involved in newborn care (Rx only).	Healthcare professionals (Rx only)
Intended Use	Measure and display heart HR	Measure, display and monitor HR
Technology		
Design	Integrated display and electrodes; lead wires unnecessary	Display and detachable leads; no electrodes
Display	LED	Thin Film Transistor (TFT) LCD
Alarm	None: Measurement only	Visual and audio alarms
HR detection method	ECG	Same
HR display range	20 bpm - 250 bpm	10 bpm - 300 bpm
HR accuracy	≤ ±1% or ±1 bpm, when tested in accordance with IEC 60601-2-27, Clause 201.12.1.101.15; data from clinical testing show that NeoBeat has an accuracy of ±3 bpm with good signal quality and ±6 bpm during reduced signal quality.	±1% or ±1 bpm, whichever is greater
Patient-contact materials	Polyamide (main body), thermoplastic polyurethane ("TPU"; main body); stainless steel (electrodes)	TPU (ECG cable)
Standards		
	AAMI/IEC 60601-1:2005 + AMD1:2012, *Medical electrical equipment - Part 1: General requirements for basic safety and essential performance*	IEC 60601-1, *Medical electrical equipment - Part I: General requirements for basic safety and essential performance, 1998; Amendment I, 1991; Amendment 2, 1995.*
	IEC 60601-1-2:2014, *Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests*	IEC 60601-1-2:2007, *Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests.*
	Not applicable	IEC 60601-2-27:2005, Medical electrical equipment - Part 2-27: *Particular requirements for the safety including essential performance, of electrocardiographic monitoring equipment.*

Discussion of Tests and Test Results

Design verification and design validation testing demonstrates that the NeoBeat Newborn Heart Rate Meter meets its functional requirements and performance specifications. In particular,

- Testing demonstrates the validation of the detection algorithm. The testing included:
    - Estimating NeoBeat's heart rate accuracy based on 19 clinical cases, including resuscitation cases, representing over 4 hours of ECG data. The 19 cases were randomly selected from a large database containing newborn ECGs from four countries outside the United States. The database contains over 1000 cases of ECGs collected from researchers using NeoBeat on both term and pre-term newborns within the first few minutes of birth, including resuscitation cases. The QRS complexes of the 19 cases were then annotated by two experts, an ICU physician and a scientific expert in ECG signal processing and analysis. Heart rate based on expert annotation was considered "ground truth". Heart rate based on NeoBeat's algorithm was then compared to the "ground truth" heart rate to determine accuracy. NeoBeat had an RMS heart rate accuracy of ±3 bpm with good signal quality and ±6 bpm during reduced signal quality.
    - Testing in accordance with applicable clauses of IEC 60601-2-27, *Particular requirements for the basic safety, and essential performance of electrocardiographic monitoring equipment*.
    - Testing on a newborn that demonstrates that electrode placement on the torso does not affect heart rate accuracy.
- Testing demonstrates that the device can be cleaned and disinfected by the reprocessing instructions given in the device labeling.
- Testing in accordance with FDA's guidance, *Applying Human Factors and Usability Engineering to Medical Devices* (February 3, 2016), demonstrates that the device is safe and effective for the intended users, uses and use environments in the United States, with respect to human factors principles as compared to the predicate.
- Testing demonstrates the device can function acceptably during its labeled expected service life.

- Testing in accordance with AAMI/IEC 60601-1:2005 + AMD1:2012, *Medical electrical equipment - Part 1: General requirements for basic safety and essential performance,* and IEC 60601-1-2:2014, *Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests,* demonstrates the electrical safety and electromagnetic compatibility of the device.

- Biocompatibility testing in accordance with FDA guidance, *Use of International Standard ISO 10993-1,* "*Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process"* (September 2020) demonstrates an appropriate biocompatibility profile for the device.

Conclusion

The results of these tests support the conclusion that the NeoBeat Newborn Heart Rate Meter performs acceptably and does not raise any different questions regarding safety or effectiveness compared to the predicate device, thus supporting a determination of substantial equivalence.