



September 22, 2026

Neko Health AB
% Brittany Valdez Nava
Senior Manager
Healthcare Innovation Catalysts, Inc.
8024 Summer Mill Court
Bethesda, Maryland 20817

Re: K254240

Trade/Device Name: Echo-2

Regulation Number: 21 CFR 870.2786

Regulation Name: Hardware And Software For Optical Camera-Based Measurement Of Pulse Rate,
Heart Rate, Breathing Rate, And/Or Respiratory Rate

Regulatory Class: Class II

Product Code: QOK

Dated: September 13, 2026

Received: September 14, 2026

Dear Brittany Valdez Nava:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.

K254240

?

Please provide the device trade name(s).

?

Echo-2

Please provide your Indications for Use below.

?

The Echo-2 device includes an optical module that is intended to capture motion-vibration signals from a illuminated skin surface for assessment of physiological information. Such information, captured during spot-measurement, includes: Heart rate.

The Echo-2 device is indicated for use by or under the supervision of healthcare professionals for adult patients in a professional healthcare setting. The Echo-2 device should be used with an individual in a supine position (including with a slightly elevated upper body). The information stored by the system may be reviewed by qualified persons.

The Echo-2 device is not intended for continuous monitoring and is only intended for spot-check measurements of heart rate. The Echo-2 device is not intended for use in subjects with arrhythmias.

Please select the types of uses (select one or both, as applicable).

☒ Prescription Use ([21 CFR 801 Subpart D](#))

☐ Over-The-Counter Use ([21 CFR 801 Subpart C](#))

?

1.0 510(K) SUMMARY

This 510(k) summary is in accordance with the requirements of the Safe Medical Device Act (SMDA) of 1990. The content of this 510(k) summary is provided in conformance with 21 CFR § 807.92.

1.1 Submitter's Information

Company Name:	Neko Health AB
Address:	Svärdvägen 19 182 33 Danderyd Sweden
Company Contact:	Per Sundström Head of Regulatory Neko Health AB Svärdvägen 19 182 33 Danderyd Sweden Phone: +46 76 344 42 34 Email: per.sundstrom@nekohealth.com
Official Correspondent:	Brittany Valdez Nava, MRSc Senior Manager Healthcare Innovation Catalysts, Inc. 8024 Summer Mill Court Bethesda, MD 20817
Date prepared:	September 13th, 2026

1.2 Subject Device Name

Trade Name:	Echo-2
Common Name:	Echo-2
Regulation Name:	Hardware and software for optical camera-based measurement of pulse rate, heart rate, breathing rate, and/or respiratory rate
Regulation Number:	21 CFR 870.2786
Device Class:	Class 2 (Special Controls)
Product Code:	QOK
Product Code Name:	Hardware and software for optical camera-based measurement of pulse rate, heart rate, breathing rate, and/or respiratory rate
510(k) Review Panel:	Cardiovascular

1.3 Legally Marketed Predicate/Reference Devices

1.3.1 Gili Pro Biosensor

The primary predicate device for the Echo-2 is the Gili Pro Biosensor cleared under DEN200038.

Submission Number DEN200038

Trade Name: Gili Pro Biosensor

Common Name: Gili Pro Biosensor, Gili Pro Biosensor System

Regulation Name: Hardware and software for optical camera-based measurement of pulse rate, heart rate, breathing rate, and/or respiratory rate

Regulation Number: 21 CFR 870.2786

Device Class: Class 2 (Special Controls)

Product Code: QOK

Product Code Name: Hardware and software for optical camera-based measurement of heart rate and respiratory rate

510(k) Review Panel: Cardiovascular

1.4 Device Description

1.4.1 Brief Description of the Device

The Echo-2 enables a non-invasive method to measure heart rate. The Echo-2 utilizes a contactless sensor approach, based on a laser vibrometer, to measure the vibrations occurring on the human skin surface caused by heart beats. The laser vibrometer detects the vibrations of the skin surface using doppler principles. The device displays the acceleration of the skin surface as a function of time and outputs heart rate as a measured numeric value.

The Echo-2 has electrical interfaces to be used in conjunction with third-party ECG devices, pulse transducers, or digital stethoscopes, should the end user want to collect auxiliary analogue data complementary to the laser vibrometer data.

The Echo-2 does not include a computer, but it shall be used with a computer compliant with the specified system requirements, running the included application software, that will control the device and output the signals.

The Echo-2 delivers electromagnetic radiation that is non-ionizing in the form of laser from its vibrometer sensor. All sources of radiation are well below limit values as stated by the applicable safety standards.

The Echo-2 is intended to be operated by qualified healthcare professionals.

1.4.2 Indications for Use

The Echo-2 device includes an optical module that is intended to capture motion-vibration signals from a illuminated skin surface for assessment of physiological information. Such information, captured during spot-measurement, includes: Heart rate.

The Echo-2 device is indicated for use by or under the supervision of healthcare professionals for adult patients in a professional healthcare setting. The Echo-2 device should be used with an individual in a supine position (including with a slightly elevated upper body). The information stored by the system may be reviewed by qualified persons.

The Echo-2 device is not intended for continuous monitoring and is only intended for spot-check measurements of heart rate. The Echo-2 device is not intended for use in subjects with arrhythmias.

1.4.3 Environment of Use

The intended use environment for the product is within clinical settings in professional healthcare facilities or other locations that fulfil appropriate requirements regarding cleanliness and controlled indoor environment. Once transported and installed by qualified personnel the device shall not be moved.

1.5 Key Performance Characteristics

The key performance specifications and characteristics of the Echo-2 are outlined in **Table 1**.

Table 1: Key Performance Characteristics

Feature	Specification/Characteristic
Technology	Contactless, laser-based measurement of micro-motions of the skin
Electrical Power Supply	Supply Source: Mains Powered Only Voltage Rating: 100 – 240 VAC, 50/60 Hz, current less than 10 A (single phase) Power rating: 230 VA
Operating Conditions	Operating Temperature: 15 to 30°C (59 to 86°F) Relative Humidity: 20 to 90% (non-condensing)
Storage and Transportation	Storage Temperature: -40 to 70°C (-40 to 158°F) Relative Humidity: 10 to 100% (including condensation) Barometric Pressure: 50 to 110kPa (7 to 16 PSI)
Expected Service Life	10 years
Laser Specifications	Class 2 Radiation Pattern/Beam Divergence: Collimated beam Wavelength: 633 nm Pulse Durations and Repetition Rate (or description of irregular pulse pattern): Continuous wave (laser frequency modulation but constant amplitude) Maximum Power/Energy Output: 1 mW
Data Transfer Method	Ethernet over optical fiber to host computer.
Data Storage	Local and Cloud storage
Data Display Method	Graphical user interface for touch display.
Displayed Calculated Parameter	- Heart Rate - signal waveform is displayed on amplitude Y-axis with time scale on X-axis
Heart Rate/Pulse Rate	Measurement Range: 25 to 220 bpm* Measurement Error: $\leq \pm 5$ bpm

* Clinical evaluation covered heart rates of approximately 40–90 bpm. Supplemental bench testing demonstrated heart rate measurement accuracy within ± 5 bpm at all 17 evaluated setpoints across the claimed range of 25–220 bpm.

1.6 Comparison of Key Technological Characteristics with the Predicate Device(s)

1.6.1 Gili Pro Biosensor

The Echo-2 is substantially equivalent to the Gili Pro Biosensor [DEN200038].

The Echo-2 (subject device) and the Gili Pro Biosensor (predicate device) have similar intended use, indications for use, fundamental scientific technology, and principles of operation. Both devices utilize optical sensing technology and software algorithms to acquire and analyze motion signals generated by cardiovascular activity to provide a spot-check measurement of heart rate in adult patients under the supervision of healthcare professionals.

Main Differences between Echo-2 and Gili Pro Biosensor

The following technical characteristics in the Echo-2 differ from those in the Gili Pro Biosensor:

- The Echo-2 utilizes laser Doppler vibrometry to measure skin surface motion, whereas the Gili Pro Biosensor uses a camera-based optical sensing approach.
- The Echo-2 displays the processed vibrometer acceleration waveform together with the measured heart rate, allowing qualified healthcare professionals to visually review the recorded physiological signal. The displayed waveform is provided as supplemental information and is not independently interpreted by the device, does not generate additional diagnostic parameters, and does not alter the intended use of the device.
- The Gili Pro Biosensor provides respiratory rate measurements, while the Echo-2 does not provide or claim respiratory rate measurement.

The differences in technological characteristics have been evaluated through performance testing and clinical validation. These evaluations demonstrate that the Echo-2 provides heart rate measurements that are substantially equivalent to the predicate device and that the differences in sensing technology, waveform presentation, and output features do not raise new or different questions of safety or effectiveness. The displayed waveform represents the processed physiological signal used to derive heart rate and serves only as supplemental information for qualified healthcare professionals reviewing the recorded measurement; it does not provide additional automated measurements or clinical interpretations beyond the cleared heart rate output.

1.7 Performance Data

1.7.1 Performance – Bench Testing

Performance testing to support the determination of substantial equivalence of the Echo-2 is summarized in **Table 2** below.

Table 2: Echo-2 Performance Testing Summary

Test Conducted	Test Objective
System Level Performance Testing	Ensure the device performs in accordance with the product requirements and design inputs
Material Verification Testing	Demonstrate that material selection, control, and validation are scientifically justified and support overall device performance and safety.
Imaging Verification	Confirm that the imaging system specified performance criteria are met under expected use conditions, with the objective of demonstrating compliance with the applicable system and use requirements
Environmental Testing	Confirms that functional environment requirements are implemented correctly and operate as intended
Servicing/Installation Testing	Confirm that the device can be correctly installed, configured, and serviced in accordance with the manufacturer's instructions, and that these activities do not adversely affect device performance or safety
Labeling Verification	Confirm that all device labels, packaging labels, and Instructions for Use (IFU) meet applicable regulatory requirements, are legible, durable, and accurately convey the intended information to the user
Heart Rate Accuracy	Verify that heart rate measurements are within ± 5 bpm of programmed reference values at evaluated setpoints across the claimed operating range of 25–220 bpm, supplementing the clinical validation.

1.7.2 Human Factors/Usability

A Usability Evaluation performed on the Echo-2 found no impact on the safe and effective use of the device compared to the predicate device. Neko Health AB concludes that the system is as safe and effective for the intended users, uses, and use environments as the predicate device.

1.7.3 Cybersecurity

Cybersecurity documentation has been provided with this application as recommended by the FDA's Guidance for Industry and FDA Staff, "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions ". All software components underwent appropriate cybersecurity assessment and testing.

1.7.4 Electrical Safety and Electromagnetic Compatibility (EMC)

The Echo-2 was evaluated for electromagnetic compatibility (EMC) in accordance with IEC 60601-1-2:2020.

Additional electrical safety testing was conducted in accordance with IEC 60601-1:2020 (Edition 3.2).

1.7.5 Radiation Safety

A comprehensive radiation safety evaluation was conducted for the device's optical emission components, including the laser vibrometer integrated into the system. The following testing was performed:

- IEC 60825-1:2020 - Safety of laser products - Part 1: Equipment classification and requirements
- System-level Radiation Hazard Assessment

Across all evaluations, the device was demonstrated to meet the applicable radiation safety requirements and does not pose hazardous levels of optical exposure under normal use.

1.7.6 Software Verification and Validation Testing

System level software verification testing were performed to demonstrate the efficacy of the software and to confirm operation of the machine. The following testing was performed:

- Functional and Performance Verification
- Regression Testing
- Code Reviews

Software verification information within this submission is provided in accordance with the following FDA guidance documents:

- Content of Premarket Submissions for Device Software Functions (14 June 2023)
- Guidance for Off-The-Shelf Software Use in Medical Devices (11 August 2023)
- Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions (26 June 2025)

1.7.7 Animal Studies

No animal studies were performed on this device.

1.7.8 Clinical Studies

A retrospective clinical performance study was conducted to evaluate the Echo-2 device's heart rate measurement performance and the clinical validity of its underlying laser Doppler vibrometry (LDV)-based sensing principles.

The retrospective study evaluated Echo-2's heart rate measurement performance by comparing LDV-derived heart rate values to electrocardiogram (ECG), a clinically accurate and widely accepted patient-contacting reference standard. The analysis used secondary data from adult participants enrolled in the Cardio Alpha and Dermaflow Alpha clinical investigations and included individuals representative of the intended use population, encompassing a broad range of ages, sexes, cardiovascular health statuses, and skin tones.

Echo-2 demonstrated strong agreement with ECG-derived heart rate measurements. Bland-Altman analysis showed mean bias and limits of agreement within predefined clinically acceptable thresholds, meeting the primary effectiveness endpoint. Deming regression analysis demonstrated slopes and intercepts consistent with equivalence expectations, confirming accurate and reproducible agreement between Echo-2 output and the reference comparator. Subgroup analyses across age, sex, and Fitzpatrick skin type showed no clinically meaningful differences in performance, supporting output consistency across demographic subgroups and expected variations in signal quality encountered in the intended use environment.

This retrospective clinical evaluation demonstrates that Echo-2 produces consistent and reliable heart rate measurements when compared with a clinically accurate patient-contacting reference device. The analyzed dataset is representative of the intended use population, selection criteria and exclusions were predefined and justified, and device output was shown to be consistent across the expected range of patient characteristics and signal conditions encountered in clinical practice.

1.8 Conclusions

Based on above discussion and enclosed sections regarding substantial equivalence to the predicate device, Neko Health AB concludes that the Echo-2 is substantially equivalent to its predicate device and does not raise any new or different questions of safety or effectiveness.