May 22, 2026

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

Re: K254129
Trade/Device Name: Spectrum-2
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: MUD
Dated: December 18, 2025
Received: December 22, 2025

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,

TANISHA L. HITHE -S
Digitally signed by TANISHA L. HITHE -S
Date: 2026.05.22 12:34:14 -04'00'

Tanisha Hithe
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical and Infection Control 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)*
K254129

Device Name
Spectrum-2

Indications for Use *(Describe)*
The Spectrum-2 device is indicated for use to record and monitor changes in oxygenation levels in superficial tissues during circulatory or perfusion examinations for individuals with potential circulatory compromise.

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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1.0 510(K) SUMMARY

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:	May 5, 2025

1.2 Subject Device Name

Trade Name:	Spectrum-2
Common Name:	Spectrum-2
Regulation Name:	Oximeter
Regulation Number:	21 CFR 870.2700
Device Class:	Class 2
Product Code:	MUD
Product Code Name:	Oximeter, Tissue Saturation
510(k) Review Panel:	General & Plastic Surgery

1.3 Legally Marketed Predicate Device

1.3.1 Clarifi Imaging System

The primary predicate device for the Spectrum-2 is the Clarifi Imaging System cleared under K181623.

510(k) Number	K181623
Trade Name:	Clarifi Imaging System
Common Name:	Clarifi Imaging System
Regulation Name:	Oximeter
Regulation Number:	21 CFR 870.2700
Device Class:	Class 2
Product Code:	MUD
Product Code Name:	Oximeter, Tissue Saturation
510(k) Review Panel:	General & Plastic Surgery

1.4 Device Description

1.4.1 Brief Description of the Device

The Spectrum-2 device is designed for contactless, non-invasive recording and monitoring of changes in concentration of haemoglobin and blood oxygenation in superficial tissues. Utilizing Spatial Frequency Domain Imaging (SFDI) technology, it employs a projector that emits light across a wavelength range of approximately 500 to 1000nm, projecting spatial frequency patterns onto the skin.

The skin's reaction to this light, in terms of absorption, reflection, and scattering, is contingent on its molecular composition. Eight cameras, each equipped with optical bandpass filters, capture the skin's response at specific wavelengths, enabling optical spectroscopy based on chromophore absorption spectra. The device identifies specific chromophores, including oxygenated haemoglobin and deoxygenated haemoglobin by mapping known absorption spectra with the measured ones.

The Spectrum-2 device includes a light engine, a digital micromirror device, optics, and cameras equipped with bandpass filters and is intended to be used as a non-invasive tissue oxygenation measurement system to capture the reflectance from skin illuminated with projected patterns that enables recording and monitoring of changes in oxygenation levels in superficial tissue.

Such information, captured during imaging measurement, includes tracking changes of:

- Oxygen saturation (StO2),
- Oxyhemoglobin (HbO2), and
- Deoxyhemoglobin (HbR)

in superficial tissue.

The device delivers electromagnetic radiation that is non-ionizing in the form of visible laser light from the 655nm Class 2 laser distance sensor (used exclusively for measuring the working distance during the positioning phase) and visible and NIR light for the projected SFDI patterns from LEDs.

- The laser is of class 2 and is considered safe for the skin and the eyes without any additional mitigations. One shall not stare into the laser. The laser source of radiation is well below limit values as stated by IEC 60825-1: Safety of laser products – Part 1.
- The LED light sources are well below limit values as stated by IEC 62471: Photobiological safety of lamps and lamp systems
- The laser is not part of the optical measurement system and does not contribute to tissue oxygenation calculations.

The device also fulfills the requirements for general safety of medical devices as described in ANSI/AAMI/IEC-60601-1: Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.

1.4.2 Indications for Use

The Spectrum-2 device is indicated for use to record and monitor changes in oxygenation levels in superficial tissues during circulatory or perfusion examinations for individuals with potential circulatory compromise.

1.4.3 Environment of Use

The Spectrum-2 device is intended for use exclusively within Neko Health clinical facilities. The device is not intended for use in other healthcare facilities or general medical practices.

Neko Health facilities are clinical environments that fulfill specific requirements regarding cleanliness, controlled indoor environment, and technical infrastructure necessary for safe and effective device operation. Once transported and installed by qualified Neko Health personnel, the device shall not be relocated.

1.5 Key Performance Characteristics

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

Table 1: Key Performance Characteristics

Feature	Specification/Characteristic
Electrical Power Supply	Supply Source: Mains-powered Voltage: 100 - 240 VAC 50/60 Hz Power Consumption: 230 VA
Operating Conditions	Ambient Temperature: 15 to 30°C (59 to 86°F) Operating Humidity: 20 to 90% RH
Storage Conditions	Storage Temperature: -40°C to 70°C (-40 to 158°F) Storage Humidity: 10 to 100%, including condensation Barometric Pressure: 50 kPa to 110 kPa
Expected Service Life	10 years
Measurement Technology	Optical, contactless SFDI (Spatial Frequency Domain Imaging)
Measurement Method	Structured illumination and spectral model-based analysis of light returned from target tissue

Feature	Specification/Characteristic
Measurements Monitored	• Oxygen saturation (StO2) • Oxyhemoglobin (HbO2) • Deoxyhemoglobin (HbR)
Measurement Sensor	The camera head is essentially the sensor part of the device, which incorporates the following main components: • 8 x machine vision cameras, one for each wavelength. • Lenses and bandpass filters for the cameras. • LED based light engine with DMD projector. • Control boards. • On-board cooling solution.
Precision	<5% error
Measurement Stability	<1% drift
Image Homogeneity	<4% roll-of
Signal-to-Noise Ratio (SNR)	>40
Measurement Time	Frame Rate: 0.5 Hz Acquisition Time for single frame: 2 seconds Recording duration interval: 2 seconds to 35 minutes
Location of Measurement	Two-dimensional area of superficial microvasculature
Laser Distance Sensor	Purpose: Working distance measurement for camera head positioning only Safety Classification: Class 2 Radiation Pattern/Beam Divergence: Collimated beam Wavelength: 655 nm Max. Power/Energy Output: 1mW Accuracy: ± 1mm Pulse Durations and Repetition Rate: the laser distance measurement module is only active during the positioning phase. During this phase the laser is running continuously distance measurements, for which each measured distance consists of 64 pairs of pulses during a timeframe of about 400ms.
Data Display	• Oxygenation map (image with color coded blood oxygenation) Blood volume map (image with color coded total hemoglobin concentration)
Data Transfer Method	Ethernet over optical fiber to host computer
Data Storage	Local and cloud-based
External Connections	Interface for monitor, ethernet
USB	At least USB 3.0 or faster

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

1.6.1 Clarifi Imaging System

The Spectrum-2 device and the Clarifi Imaging System are both non-invasive, non-contact optical imaging systems that utilize multispectral illumination and spectral analysis of reflected or remitted light to assess tissue oxygenation and hemoglobin-related parameters in superficial biological tissue, including oxygen saturation (StO_2), oxyhemoglobin (HbO_2), and deoxyhemoglobin (HbR).

Both systems utilize Spatial Frequency Domain Imaging (SFDI) principles, projecting spatially-modulated light patterns onto tissue and measuring the resulting reflectance to determine optical absorption and scattering properties. Functionally, both devices incorporate a light engine, projection module/DMD, optics, and cameras with wavelength-specific filters, which may enable quantitative assessment of tissue chromophores.

Main Differences between Spectrum-2 and Clarifi Imaging System [K181623]

The differences between the Spectrum-2 and the predicate device are limited to component-level implementation, including light source configuration, wavelength selection, and imaging hardware. Both devices rely on the same fundamental SFDI-based optical principles and analytical methods to derive tissue oxygenation parameters.

- Measurement and Optical Acquisition Approach
    - The Spectrum-2 employs a projector that emits light of various wavelengths and patterns of various spatial frequencies with a dependency on the skin's molecular composition and structure within the examined skin volume. Cameras are then used to image the reflected light per illuminated wavelength (approximately 500 to 1000nm), and the data is used to model the skin scattering and absorption properties for collecting oxygenation data.
    - The Clarifi Imaging System uses discrete visible and near-infrared wavelengths between 450 and 1000 nm and a complementary metal oxide semiconductor (CMOS) camera for collecting hyperspectral images. Clarifi also uses a projector, a number of LEDs and camera technologies similar to that of Spectrum-2, being the difference between them the number of LEDs, the specific discrete wavelengths used, and the number of cameras.

Importantly, the Spectrum-2's intended use is within the scope of the predicate device's intended use, as it is limited to recording and monitoring changes in tissue oxygenation in superficial tissues during circulatory or perfusion assessments. The Spectrum-2 does not expand the clinical use beyond that of the predicate and does not introduce new types of outputs, diagnostic claims, or user populations that would alter the risk profile.

The differences in technological characteristics have been evaluated through performance bench testing. The results of these studies verify that these differences do not raise new or different questions of safety and effectiveness when the Spectrum-2 is used as intended.

1.7 Performance Data

1.7.1 Performance – Bench Testing

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

Table 2: Spectrum-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.
Inter-scanner Variability	Evaluates whether multiple Spectrum-2 scanners produce consistent absorption-coefficient and chromophore-concentration measurements by comparing inter-device variability against predefined acceptance criteria
Resolution Verification	Evaluates the Spectrum-2 device's precision, stability, homogeneity, and signal-to-noise ratio using diffuse reflectance scans of tissue-mimicking phantoms to confirm that its performance meets the acceptance criteria established for substantial equivalence to the predicate device
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

1.7.2 Human Factors Validation Testing

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

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 Spectrum-2 was evaluated for electromagnetic compatibility (EMC) in accordance with IEC 60601-1-2 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests.

Additional electrical safety testing was conducted in accordance with IEC 60601-1 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.

1.7.5 Radiation Safety

A comprehensive radiation safety evaluation was conducted for the device's optical emission components, including all visible LEDs used for illumination and the laser distance sensor integrated into the system. The following testing was performed:

- IEC 62471:2006 - Photobiological safety of lamps and lamp systems
- 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

Two retrospective clinical studies were conducted to evaluate Spectrum-2's performance and underlying measurement principles.

The first study compared Spectrum-2 to a research device to assess sensitivity to circulatory compromise. Spectrum-2 successfully detected reductions in tissue oxygen saturation (StO_2) during vascular occlusion and subsequent increases after release, meeting the primary effectiveness endpoint. Spectrum-2 demonstrated highly statistically significant changes between baseline and compromised states, confirming sensitivity to circulatory compromise.

Regression analysis showed strong agreement between Spectrum-2 and the research device, with slopes and intercepts consistent with equivalence expectations, satisfying the first secondary effectiveness endpoint.

The second retrospective study analyzed data from 2 clinical investigations, Spectrum-1 and Dermaflow Alpha, to validate the spatial frequency domain imaging (SFDI) technique and assess demographic factors such as skin tone, age, and sex. Results confirmed that the measurement method integral to Spectrum-2 remains valid and clinically relevant across diverse populations. Observed differences were consistent with literature expectations and did not raise new safety or effectiveness concerns.

1.8 Conclusions

Based on above discussions and enclosed sections regarding substantial equivalence, Neko Health AB concludes that the Spectrum-2 does not raise any new or different questions of safety or effectiveness and is therefore substantially equivalent to the Clarifi Imaging System.