May 20, 2026

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

Re: K253911
Trade/Device Name: Derma-2
Regulation Number: 21 CFR 884.2980
Regulation Name: Telethermographic System
Regulatory Class: Class I, reserved
Product Code: LHQ, FTT
Dated: April 24, 2026
Received: April 24, 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,

YANNA S. KANG -S

Yanna Kang, Ph.D.
Assistant Director
Mammography and Ultrasound Team
DHT8C: Division of Radiological
Imaging and Radiation Therapy Devices
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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.	K253911

Please provide the device trade name(s).

Derma-2

Please provide your Indications for Use below.

The Derma-2 device is intended for adjunctive use in addition to other clinical methods and procedures for visually and thermally significant indications of an individual's skin.

The Derma-2 device is intended for displaying, reviewing, and reporting of images of the skin as well as temperature patterns and changes. The significance of these images and thermal patterns is determined by professional investigation.

The Derma-2 device is not intended for absolute temperature measurements. The system is not intended to be used as a thermometry device. The Derma-2 device is intended for use by trained personnel.

The Derma-2 system provides relative surface temperature information only. The device does not identify anatomical structures. Interpretation of thermal patterns remains solely the responsibility of the qualified healthcare professional.

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 K253911

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:	December 6, 2025

1.2 Subject Device Name

Trade Name:	Derma-2
Common Name:	Derma-2
Regulation Name:	Telethermographic System
Regulation Number:	21 CFR 884.2980
Device Class:	Class 1
Product Code:	LHQ
Product Code Name:	System, Telethermographic (Adjunctive Use)
Add. Product Code:	FTT (21 CFR 878.4160)
510(k) Review Panel:	Radiology

1.3 Legally Marketed Predicate Device

1.3.1 Thermidas IR System (ThIR-A615)

The primary predicate device for the Derma-2 is the Thermidas IR System (ThIR-A615) cleared under K200999.

510(k) Number	K200999
Trade Name:	Thermidas IR System (ThIR-A615)
Common Name:	Thermidas IR System
Regulation Name:	Telethermographic System
Regulation Number:	21 CFR 884.2980
Device Class:	Class 1
Product Code:	LHQ
Product Code Name:	System, Telethermographic (Adjunctive Use)
510(k) Review Panel:	Radiology

1.4 Device Description

1.4.1 Brief Written Description of the Device

The Derma-2 is a telethermographic system (adjunctive use). It is similar to other legally marketed adjunctive use telethermographic systems.

The Derma-2 is a telethermographic imaging system intended for adjunctive use in professional healthcare settings to capture and display high-resolution color and thermal images of the skin surface. The device provides photographic and thermographic image datasets that may be reviewed by healthcare professionals as part of clinical documentation, diagnosis, and evaluation workflows.

The Derma-2 consists of an imaging chamber that includes multiple imaging modules that acquire color and thermal images of the subject's skin in a contactless manner containing multiple imaging modules, including visible spectrum cameras, infrared thermal cameras, and depth-sensing cameras. These components operate together to capture comprehensive image datasets of the skin surface in a contactless manner. System software coordinates image acquisition, processes image data, and presents the resulting images for visualization, review, and documentation by trained healthcare personnel.

The system incorporates visible light (LED) illumination to support high-resolution color imaging. In addition, the system includes depth-sensing (Time-of-Flight) sensors that are used exclusively to support subject positioning, acquisition geometry verification, and automated focus control. The depth-sensing subsystem does not generate clinical images, does not provide anatomical reconstruction, and is not used for diagnostic or analytical purposes.

Following acquisition, imaging data are encrypted and securely stored for clinical review. Thermal images produced by the system represent relative temperature patterns and variations across the skin surface and are intended for adjunctive evaluation and clinical interpretation by a healthcare professional. The device is not intended to measure or report absolute temperature values and does not provide diagnostic interpretation or automated clinical decision-making.

The Derma-2 delivers non-ionizing electromagnetic radiation in the form of visible LED illumination and incorporates Class 1 near-infrared emitters used for distance sensing and system positioning functions.

1.4.2 Indications for Use

The Derma-2 device is intended for adjunctive use in addition to other clinical methods and procedures for visually and thermally significant indications of an individual's skin.

The Derma-2 device is intended for displaying, reviewing, and reporting of images of the skin as well as temperature patterns and changes. The significance of these images and thermal patterns is determined by professional investigation.

The Derma-2 device is not intended for absolute temperature measurements. The system is not intended to be used as a thermometry device. The Derma-2 device is intended for use by trained personnel.

The Derma-2 system provides relative surface temperature information only. The device does not identify anatomical structures. Interpretation of thermal patterns remains solely the responsibility of the qualified healthcare professional.

1.4.3 Environment of Use

The Derma-2 (including its components) is intended for use in professional healthcare facilities, specifically Neko Health-owned and operated clinics, by Neko Health trained personnel. 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 Derma-2 are outlined in **Table 1**.

Table 1: Key Performance Characteristics

Feature	Specification/Characteristic
Accessories/ Components	The system is constructed using 9 imaging modules, where each module includes two sub-modules: • 2D high resolution imaging module, including controllable lens for focusing and controllable mirror to adjust field of view. • ToF camera (based on "Time-of-Flight" principles) To support the high-resolution cameras with sufficient and reproducible lightning conditions, the system also incorporates 24 illumination-modules, which uses LED technology. Finally, there are 12 thermal imaging modules, or IR-cameras.
Electrical Power Supply	Supply Source: Mains Powered Rating: 100 to 240 VAC, 50 to 60 Hz Power Consumption: 2000 VA
Operating Conditions	Operating Temperature: 15 to 30ºC (59 to 86ºF) Operating Humidity: 20 to 90% RH, non-condensing
Storage Conditions	Storage Temperature: -40°C to 70°C (-40 to 158ºF) Storage Humidity: 10 to 100%, including condensation Barometric Pressure: 50 kPa to 110 kPa (7.3 to 15.95 PSI)
Expected Service Life	10 years
IR Resolution	464 × 348 resolution
Infrared Camera(s)	**FLIR A50** **Focal Plane Array (FPA)**: Uncooled microbolometer **Detector Pitch:** 17 µm **Field of View (FOV):** 51° × 39° **Minimum Focus Distance:** 0.2 m (0.66 ft) **Spatial Resolution:** 1.5 mrad/pixel **Image Frequency:** 30 Hz **IR Resolution:** 464 × 348 resolution **Spectral Range:** 7.5–14.0µm **Thermal Sensitivity:** <35 mK
Relative Temperature Accuracy	The thermal imaging system measures relative surface-temperature differences within an accuracy of ±1 °C across the temperature range of 30 °C to 45 °C, when operated under the specified operating conditions above. Recommended thermal-imaging conditions 20–25 °C / 30–70 % RH).

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

1.6.1 Thermidas IR System (ThIR-A615)

The Derma-2 is substantially equivalent to the Thermidas IR System (ThIR-A615) [K200999].

The Derma-2 is a non-contact imaging device intended for adjunctive use in the visualization of relative skin temperature patterns across the human body. The device utilizes infrared (thermal), color, and three-dimensional imaging modalities to capture comprehensive surface information of the subject's skin. The Derma-2 System is compared to the predicate device, the Thermidas IR System (ThIR-A615, K200999), with respect to the thermographic imaging functionality of the device. The Thermidas IR System is likewise intended for adjunctive, non-diagnostic thermographic imaging of skin regions.

Both devices employ non-contact, passive infrared imaging used to observe relative thermal distributions for clinical review by trained personnel. Neither system is intended for absolute temperature measurement or diagnostic interpretation. The thermographic functionality of the Derma-2 operates under the same fundamental scientific principles as the predicate device and supports the same adjunctive visualization purpose.

Main Differences between Derma-2 and Thermidas IR System

The following technical characteristics in the Derma-2 differ from those in the Thermidas IR System:

- Technologically, both systems employ uncooled infrared cameras to acquire thermal images of the skin surface. The Derma-2 integrates multiple IR cameras within a modular array to achieve full-body coverage compared to the predicate device.
- The Thermidas IR System is battery powered, while the Derma-2 system requires a connection to the facilities' mains power supply.
- In addition to thermographic imaging, the Derma-2 incorporates visible light color imaging and depth-sensing modules that are not present in the predicate device. The visible light color imaging functionality is a 510(k)-exempt imaging function operating under a separate classification regulation. The depth-sensing module is a non-device component used to provide supplementary spatial context and is outside the scope of this clearance. These additional imaging modalities do not alter the thermographic imaging functionality or intended adjunctive use of the device.

The differences in the thermographic technological characteristics have been evaluated through performance bench testing, including assessment of thermal imaging performance and system functionality. The results of these tests verify that these differences do not raise new or different questions of safety and effectiveness when the Derma-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 Derma-2 is summarized in **Table 2**.

Table 2: Derma-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 (excluding the thermal camera system) specified performance criteria are met under expected use conditions, with the objective of demonstrating compliance with the applicable system and use requirements
Thermal Imaging Verification	Confirm that the thermal camera imaging system specified performance criteria are met under expected use conditions, with the objective of demonstrating compliance with the applicable system and use requirements
Relative Temperature Performance	Confirm that the thermal imaging system's relative temperature measurement performance meets specified accuracy criteria across the intended operating range, by comparing measured temperature differences between calibrated black-body targets under controlled conditions representative of clinical use
Noise Level Testing	Ensure that the sound emitted by the device is within safe and acceptable limits for human exposure, preventing hearing damage or discomfort during use.
Installation Testing	Ensures that the Installation Manual provides adequate and correct instructions for the proper installation of the device in accordance with safety and operational requirements
Environmental Testing	Confirms that functional environment requirements are implemented correctly and operate as intended
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/Usability

A Usability Evaluation performed on the Derma-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 the software components underwent appropriate cybersecurity assessment and testing.

1.7.4 Electrical Safety and Electromagnetic Compatibility (EMC)

The Derma-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.

The Derma-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.

Relevant testing was performed by an FDA ASCA-accredited laboratory under the Accreditation Scheme for Conformity Assessment (ASCA), and the resulting reports conform to FDA’s ASCA program requirements.

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 near-infrared Time-of-Flight (ToF) laser module integrated into the system. The following testing was performed:

- IEC 62471:2006 - Photobiological safety of lamps and lamp systems
- IEC 60825-1:2014 - 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

Clinical studies were not performed on the device.

1.8 Conclusions

Based on above discussion and enclosed sections regarding substantial equivalence to the predicate device, Neko Health AB concludes that the Derma-2 is substantially equivalent to the Thermidas IR System (ThIR-A615) and does not raise any new or different questions of safety or effectiveness.