November 29, 2024

Movano Inc. dba Movano Health
Kim Tompkins
VP, Quality, Regulatory, & Clinical (QRC)
6800 Koll Center Parkway, Suite 160
Pleasanton, California 94566

Re: K241090
Trade/Device Name: Evie Med Ring
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: DQA
Dated: November 4, 2024
Received: November 4, 2024

Dear Kim Tompkins:

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,

James J. Lee -S

for Bradley Quinn
Assistant Director
DHT1C: Division of Anesthesia,
Respiratory, and Sleep Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT, and Dental 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.

Submission Number *(if known)*

K241090

Device Name

EvieMED Ring

Indications for Use *(Describe)*

EvieMED Ring is a wireless, non-invasive, and stand-alone pulse oximeter intended to be used for spot checking oxygen saturation of peripheral arterial hemoglobin (SpO2) and pulse rate of adult users with a condition that might benefit from monitoring. Only the Pulse Oximeter function of the EvieMED device provides medical data. The device is designed for use in a healthcare or home environment, during no motion conditions. It is not intended for critical care and out-of-hospital transport use and does not have alarms. It is available with a prescription and can aid in the diagnosis and treatment of health conditions.

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.

Submitter Legal Manufacturer Specification Developer	Movano Inc. dba Movano Health 6800 Koll Center Parkway, Suite 160 Pleasanton, CA 94566 USA
Date Prepared	November 27, 2024
Contact	Kim Tompkins VP, QRC Movano Inc. dba Movano Health Email: ktompkins@movano.com Phone: 408 981 4889 Fax: 925 596 7100
Trade Name	EvieMED Ring
Common Name	Pulse Oximeter
Classification	21 CFR 870.2700 Class II
Product Code	DQA
Establishment Registration Number	NA
Predicate Device	Biobeat Watch K181006
Reference Predicate	Belun Ring K211407

Device Description

The EvieMED Ring is a rechargeable noninvasive wearable. The wearable is an open arrow design that allows for a snug fit and comfort during fluctuations in fluid retention and/or weight changes. There is an optical sensor that collects physiological signals and an app that processes the signals and provides spot SpO2 and pulse rate (PR) measurements during a spot check on a user's connected iOS phone. The ring is designed to be worn continuously and is waterproof, allowing the user to wear the device during handwashing, showering, and bathing without damaging the ring.

The EvieMED Ring is designed for accurate pulse oximeter readings inside and outside of a clinical setting. The device is for a single user but can be used for many users, with the rechargeable battery in the ring and the charger expected to last 2 years or more. The device is not life-sustaining or life-supporting and does not include alarms. It is not indicated for use in motion or in conditions of low perfusion.

The device is supplied in a labeled box that includes a wearable, a charger, a USB-C cable, and a quick start guide. The ring is provided in common ring sizes (e.g., US 5 through US 12). Operation of the device depends on connection to the user’s device running iOS 16.0 and above where the EvieMED Ring Mobile Application has been installed and registered, and a user-supplied AC adaptor is required for recharging the charger.

Intended Use/Indications for Use

EvieMED Ring is a wireless, non-invasive, and stand-alone pulse oximeter intended to be used for spot checking oxygen saturation of peripheral arterial hemoglobin (SpO2) and pulse rate of adult users with a condition that might benefit from monitoring. Only the Pulse Oximeter function of the EvieMED device provides medical data. The device is designed for use in a healthcare or home environment, during no motion conditions. It is not intended for critical care and out-of-hospital transport use and does not have alarms. It is available with a prescription and can aid in the diagnosis and treatment of health conditions.

Technological Characteristics

Operating Principles

Pulse oximetry of the EvieMED Ring is based upon the fundamental principle that hemoglobin bound to oxygen (oxyhemoglobin) and hemoglobin unbound to oxygen (deoxyhemoglobin) vary in the absorption of different wavelengths of light and the absorption can be used to estimate SpO2 and PR. *Intended Use*

The Evie Ring is a wireless, non-invasive, and stand-alone pulse oximeter intended to be used for spot checking oxygen saturation of peripheral arterial hemoglobin (SpO2) and pulse rate of adult users in a healthcare or home environment, during no motion conditions. It is not intended for critical care and out-of-hospital transport use and does not have alarms.

Mechanism of Action

Pulse oximetry using the EvieMED Ring can be performed with the ring worn on the patient's finger or held in place at the fingertip. Optical sensors within the ring transmit to and receive light from the tissue using a photodetector that detects the signal variation resulting from differences in the absorption of light. Signals are then passed to the user's connected iOS device where they are processed to provide a spot check SpO2 and pulse rate.

Comparison Summary of Technological Characteristics

Similarities and Differences: Subject and Predicate Devices

Description		**Subject Device:** **EvieMED [Movano Health] Ring Pulse Oximeter**	**Predicate Device:** **Biobeat Pulse Oximeter K181006**	**Reference Predicate Device:** **Belun Ring BLR-100X K211407**
Regulatory Details	Regulatory	Class II DQA	Class II DQA	Class II DQA
	Intended Use	EvieMED Ring is a wireless, non-invasive, and stand-alone pulse oximeter intended to be used for spot checking oxygen saturation of peripheral arterial hemoglobin (SpO2) and pulse rate of adult users with a condition that might benefit from monitoring. **Only the Pulse Oximeter function of the EvieMED device provides medical data.** The device is designed for use in a healthcare or home environment, during no motion conditions. It is not intended for critical care and out-of-hospital transport use and does not have alarms. It is available with a prescription and can aid in the diagnosis and treatment of health conditions.	The BB-613 Watch Oximeter is a small, wrist-worn device indicated for use in measuring and displaying functional oxygen saturation of arterial hemoglobin (%SpO2) and pulse rate. It is intended for spot-checking of adult patients in hospitals, clinics, long-term care, and home use.	Belun Ring BLR-100X is a wireless, non-invasive and stand-alone pulse oximeter intended to be used for continuous data collection and recording of oxygen saturation of arterial hemoglobin (SpO2) and the pulse rate of adult patients through index finger in hospital and home environment for up to ten hours, during no motion and motion conditions, and for patients who are well or poorly perfused. It is not intended for single-use and out-of-hospital transport use and does not have alarms.
	Availability	Rx	Rx	Rx
Intended Use Comparison Discussion: Similar intended patient population and pulse oximetry use. Both the subject device and the predicate device are indicated for spot checking SpO2 and pulse during non-motion. All can be used in a home environment. "Not intended for out of hospital transport use" is the same as the reference device. "Not intended for use in critical care" and "as an aid in diagnosis and treatment" are prescribing information that is important for the safety of the patient. Medical data function (in bold), while not included in the predicate or reference device's intended use was added to the subject device to ensure safety following usability testing.				

Description		**Subject Device:** **EvieMED [Movano Health] Ring Pulse Oximeter**	**Predicate Device:** **Biobeat Pulse Oximeter K181006** See Attachments 12-1, 12-2, & 12-3	**Reference Predicate Device:** **Belun Ring BLR-100X K211407** See Attachments 12-4, 12-5, & 12-6
Technology	Measure-ment site	Finger/fingertip	Wrist	Finger
	Data collection	Spot check	Spot check	Continuous
	Principle of operation	Pulse Reflective: green, red, and IR LEDs	Pulse Reflective: red and IR LEDs	Pulse Reflective: multi-wavelength
	Users	Single user or multi-user [patients]	Single patient use	Multi-patient use
	User interface	Mobile application software (app) installed on a user-supplied compatible phone.	LCD on device	Not specified
	Form factor	Ring wearable or fingertip	Wrist wearable	Ring wearable
	How supplied	Supplied and used non-sterile	Supplied and used non-sterile	Supplied and used non-sterile
	Data storage	Yes	No	Yes

Technology Discussion: The form factor for the subject device is a ring and the predicate device is a watch; the reference device is a ring device cleared for continuous pulse oximetry use. All devices are wearable, with the same principle of operation. The subject device is for a single user or multi-user, while the predicate device is only for single patient use, and the reference device is for multi-patient use. The key difference is the user interface screen display for the subject device and direct display for the predicate device. This difference has been tested in clinical and bench testing for the subject device and found to be safe and effective for its intended use. The additional wellness features of the subject device have no impact on the medical device pulse oximeter function—these features are exempt under the wellness policy and/or enforcement discretion as a multi-function device.

Description		**Subject Device:** **EvieMED [Movano Health] Ring Pulse Oximeter**	**Predicate Device:** **Biobeat Pulse Oximeter K181006** See Attachments 12-1, 12-2, & 12-3	**Reference Predicate Device:** **Belun Ring BLR-100X K211407** See Attachments 12-4, 12-5, & 12-6
Design and Material Specs	Commun-ication	Communication between the wearable and the App using Bluetooth Low Energy (BLE).	Not specified	Communication between the wearable and the App using Bluetooth 4.2 or above; 5.0 or above is preferred.
	Material, contact	Outer ring: amorphous metal Inner ring: polymer	Polycarbonate, silicone	Ring: thermoplastic elastomers and polycarbonates.
	Power	Rechargeable battery powered	Battery powered	Battery powered
	Operating Temp-erature	5°C to 40°C (41°F to 104° F) Ambient	4°C to 39°C (39°F to 103°F)	• Keep Belun" Ring away from dust, lint, vibration, corrosive substances, explosive materials, high temperature and moisture • When Belun" Ring is carried from cold environment to warm or humid environment, do not use it immediately.
Design and Material Specifications Discussion: All devices are battery-powered wearables and communication between the wearable and the mobile app depends on Bluetooth for both the subject and the reference device. Materials are all common skin contacting materials. Operating temperature are similar between the primary predicate and the subject device while the reference predicate does not have specified temperatures but has implied ambient room temperature from the information provided. The key difference between the subject device and the predicate device is the form factor, which is the same between the subject and the reference devices. Differences in the form factor and materials have been tested and essential performance demonstrated,				
Accuracy Validation	SpO2 accuracy	+/- 3.5% over the range of 70 to 100%.	+/- 3% over the range of 70 to 100%.	+/- 2.7% over the range of 70 to 100%
	Pulse rate accuracy	+/- 3 bpm over the range of 40 to 240	+/- 3% over the range of 40 to 240 bpm	+/- 2.5 bpm or 2% whichever is larger over the range 30 to 250 bpm.
Accuracy: Accuracy specifications are similar for all three devices with the only difference that the reference device has a broader range for pulse. All are within the accuracy for SpO2 specified in the pulse oximeter guidance.				

Technological Comparison Summary

The form factor for the subject device is a ring and the predicate device is a watch; the reference device is a ring device cleared for continuous pulse oximetry use. All devices are wearable, with the same principle of operation. The subject device is for a single user or multi-user, while the predicate device is only for single patient use, and the reference device is for multi-patient use. The key difference is the user interface with a screen display for the subject device and direct display for the predicate device. Both the subject device and the reference device include wellness features. Differences

have been tested in clinical, usability, biocompatibility, and bench testing for the subject device and found to be safe and effective for its intended use.

Non-Clinical and Clinical Tests Summary & Conclusions

The following performance testing was completed to demonstrate substantial equivalence:

- Electrical safety, EMC, and home safety testing per IEC 60601-1, 62133, 60601-1-2, and 60601-1-11
- Usability testing per IEC 62133
- Software validation per FDA guidance including cybersecurity
- Bench study pulse accuracy was completed per IEC 80601-2-61
- Cytotoxicity, sensitization, and irritation testing per ISO 10993-1, ISO 10993-5, and ISO 10993-11 to evaluate the permanent contact of a copolyester and LiquidMetal™ with intact skin was completed.

Clinical validation per IEC 60601-2-61 and FDA guidance was completed in an IRB-approved SpO2 accuracy study at an independent lab. Eleven (3 male, 7 female) healthy young adults were enrolled into the study with 4 rings/subject. Subjects were evaluated per the Fitzpatrick scale with 3/11 in group I/II 5/11 in group III/IV, and 3/11 in group V/VI. There were no deviations or adverse events for the 11 subjects. Test devices and reference devices were placed and an arterial line started in one wrist. Subjects were placed into controlled hypoxia from 100% to 70%. SaO2 and test samples were taken at baseline (1) and then four samples at each decile (90's, 80's, and 70's) for two runs for a total of approximately 25 samples/subject. SaO2 data was compared to the test (SpO2) data and the root mean square error calculated. Paired samples were evaluated for each test placement site, by gender, and by Fitzpatrick group, and finally pooled together over the range of 70-100%. By placement site, accuracy met the acceptance criteria of less than 3.5%. By gender, the range varied by placement with all below the 3.5% acceptance criteria. By Fitzpatrick scale, accuracy varied by placement but no trends were identified for Fitzpatrick V/VI and all were under the 3.5% threshold. All samples (816) were pooled for an overall accuracy of 2.46%.

Conclusions

The EvieMED Ring is as safe and as effective as the Biobeat BB-613 Watch Oximeter. The EvieMED Ring has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. The minor differences in indications do not alter the intended diagnostic use of the device when used as labeled. In addition, the minor technological differences between the EvieMED Ring and its predicate devices do not raise different questions of safety or effectiveness. Performance data from the nonclinical and clinical tests demonstrated that the test device is as safe, as effective, and performs as well or better than the legally marketed predicate devices identified. Thus, the EvieMED Ring pulse oximeter is substantially equivalent.