September 24, 2024

Happy Health Inc.
% Rakesh Lal
Consultant
Rx Device Consulting
7 Courtyard Pl
Lexington, Massachusetts 02420

Re: K240236
Trade/Device Name: Happy Ring Health Monitoring System
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac monitor (including cardiotachometer and rate alarm)
Regulatory Class: Class II
Product Code: MWI, DQA, FLL, DRG
Dated: January 10, 2024
Received: January 29, 2024

Dear Rakesh Lal:

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,

Jennifer W. Shih -S

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

K240236

Device Name

Happy Ring Health Monitoring System

Indications for Use *(Describe)*

The Happy Ring Health Monitoring System is a wearable device system to remotely monitor physiologic parameters of patients in professional healthcare facilities, such as hospitals or skilled nursing facilities, or their own home. The device is intended for use on individuals who are 22 years of age or older.

The device supports continuous data collection for monitoring of the following physiological parameters:
- Acceleration / Movement
- Electrodermal Activity (EDA)
- Blood Oxygen Saturation
- Pulse Rate
- Peripheral Skin Temperature

The Happy Ring Health Monitoring System is intended for peripheral skin temperature monitoring, where monitoring temperature at the finger is clinically indicated.

The Happy Ring Health Monitoring System is not intended for SpO2, pulse rate, respiration rate monitoring in conditions of motion or low perfusion.

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) #: K240236

510(k) Summary

Prepared on: 2024-08-21

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Happy Health Inc.
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Correspondent Contact	Mr. Rakesh Lal
Correspondent Contact Email	rakesh@rxdeviceconsulting.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Happy Ring Health Monitoring System
Common Name	Cardiac monitor (including cardiotachometer and rate alarm)
Classification Name	Monitor, Physiological, Patient (Without Arrhythmia Detection Or Alarms)
Regulation Number	870.2300
Product Code	MWI

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K230457	Empatica Health Monitoring Platform; EmbracePlus; Empatica C	MWI

Device Description Summary

21 CFR 807.92(a)(4)

The Happy Ring Health Monitoring System is a wearable device and software platform comprising:
- A wearable medical device smart ring,
- A mobile app-based bluetooth-to-internet gateway,
- A cloud-based API,
- A set of data processing algorithms, and
- A Physician data viewer.

The Ring is worn on the user's finger and continuously collects raw data via specific sensors. These raw data are transmitted via Bluetooth Low Energy to a paired mobile device. The data received are transmitted by the mobile app gateway, via the cloud-based API, to the data processing algorithms where various physiological parameters are computed. The raw and processed data are stored, further analyzed, and accessible by healthcare providers or researchers via the Physician data viewer.

The Happy Ring Health Monitoring System is intended for retrospective remote monitoring of physiological parameters in ambulatory adults in home-healthcare environments. It is designed to continuously collect data to support intermittent monitoring of the following physiological parameters and digital biomarkers by trained healthcare professionals or researchers: Acceleration / movement, electrodermal activity (EDA), blood oxygen saturation, pulse rate, and peripheral skin temperature.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The Happy Ring Health Monitoring System is a wearable device system to remotely monitor physiologic parameters of patients in professional healthcare facilities, such as hospitals or skilled nursing facilities, or their own home. The device is intended for use on individuals who are 22 years of age or older.

The device supports continuous data collection for monitoring of the following physiological parameters:
- Acceleration / Movement
- Electrodermal Activity (EDA)
- Blood Oxygen Saturation
- Pulse Rate
- Peripheral Skin Temperature

The Happy Ring Health Monitoring System is intended for peripheral skin temperature monitoring, where monitoring temperature at the finger is clinically indicated.

The Happy Ring Health Monitoring System is not intended for SpO2 or pulse rate monitoring in conditions of motion or low perfusion.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The subject device and predicate device have very similar indications for use, and therefore have the same intended use. Both devices are intended to measure various physiological parameters in adults (18 years of age or older) in home or healthcare facilities for the purpose of retrospective review by a clinician or researcher. In particular, both devices measure blood oxygen saturation, pulse rate, peripheral skin temperature, and electrodermal activity. The subject device measures acceleration while the predicate device measures activity associated with movement during sleep. This minor difference in indications for use does not constitute a new intended use.

Technological Comparison

21 CFR 807.92(a)(6)

The subject device and predicate device both have very similar technological characteristics. Both devices include a wearable sensor that acquires various raw signals, and transmits these raw signals to a cloud application via a mobile application. The communication between wearable device and mobile application occurs via Bluetooth Low Energy and the communication between mobile application and cloud application occurs via Wi-Fi or cellular for both devices. For both devices, raw signal data are processed to determine and display various physiological measures (pulse rate, blood oxygen saturation, peripheral skin temperature, and electrodermal activity), and for these measures, the technical method to determine the measures are similar. Both devices power the wearable sensor via a rechargeable lithium battery. Both devices include software, and include user interfaces for patient and clinician.

Some minor differences in technological characteristics exist between the two devices. The specific implementation of the software within each device is different but this does not raise different questions of safety and effectiveness as the general function of the software within each device is similar. The specific models of the sensors used by each device may be different, but this also does not raise different questions of safety and effectiveness as the sensors (PPG, Temperature, EDA) acquire the same general raw signal data.

The subject device's wearable sensor is a smart ring worn on the patient's finger whereas the predicate device is a wrist worn smart watch. Both devices measure their respective physiological signals with appropriate accuracy and precision, and as a result, this difference in anatomical site for acquiring raw signal data does not raise different questions of safety and effectiveness. The subject device also does not include a screen on the wearable sensor whereas the predicate device does. All relevant information is available on other screens accessible to patient (mobile application) and clinician (Physician data viewer), and as a result, this difference does not raise different questions of safety and effectiveness.

On this basis, the subject and predicate device can be considered substantially equivalent.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

The following non-clinical tests were performed on the Happy Ring Health Monitoring System.

- Electrical, mechanical and thermal safety testing in accordance with IEC 60601-1 and IEC 60601-1-11.

- Electromagnetic Compatibility testing in accordance with IEC 60601-1-2.

- Wireless coexistence testing in accordance with FDA's guidance: Radio Frequency Wireless Technology in Medical Devices.

- Usability testing in accordance with IEC 62366 and FDA's guidance: Applying Human Factors and Usability Engineering to Medical Devices.

- SpO2 and Pulse Rate bench testing in accordance with ISO 80601-2-61.

- Temperature measurement accuracy testing in accordance with the relevant sections of ISO 80601-2-56.

- Bench testing to verify the performance of EDA and accelerometer sensors.

- Software V&V testing and Cybersecurity. Documentation was provided as recommended by FDA's guidance: Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, and Content of Premarket Submissions for Management of Cybersecurity in Medical Devices.

The following clinical tests were performed on the Happy Ring Health Monitoring System.

- Pulse Oximetry: blood oxygen saturation data from 12 subjects of varying BMI, skin tone, and ring size, all wearing the subject device were compared against oxyhemoglobin saturation using a radial arterial line, in accordance with ISO 80601-2-61. The data demonstrates that the subject device's blood oxygen saturation measurements was within 3.5% Arms for the range of oxygen saturation measured by the device. No adverse events were reported during the trial.

Based on the information presented in this 510(k) premarket notification, device performance and safety evaluated in clinical testing, and comparison with the legally marketed predicate device, the Happy Ring Health Monitoring Platform has been shown to be substantially equivalent to the legally marketed predicate device.