February 9, 2024

Neteera Technologies Ltd.
Rakefet Shohat
VP QA/RA/CA
Prof Rakah 3 St.
Jerusalem, Jerusalem 9139002
Israel

Re: K231733
Trade/Device Name: Neteera 130H-Plus Vital Sign Monitoring Sensor
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (Including Cardiotachometer And Rate Alarm)
Regulatory Class: Class II
Product Code: DRT, BZQ
Dated: January 11, 2024
Received: January 11, 2024

Dear Rakefet Shohat:

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.

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,

for Hetal B. Odobasic -S

Jennifer Shih 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below

510(k) Number *(if known)*

K231733

Device Name

Neteera 130H-Plus

Indications for Use *(Describe)*

The Neteera 130H-Plus device is intended for spot and continuous measurement of heart rate and respiration rate in adult patients (in healthcare facilities and home monitoring) and inform on bed exit.

The indications provided are to be used by health care professionals and are intended to be reviewed by clinicians to inform patient care.

The Neteera device is not intended to be used as an alarm system for potentially acute life-threatening situations in which medical intervention is necessary (e.g., ICU).

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.

510(k) Summary

Device Name: Neteera 130H-Plus
Vital Signs Monitoring Sensor

1. **510K Submission Sponsor**

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2. **Date Prepared**
9-Jan 2024

3. **Device Identification**

Trade/Proprietary Name: Neteera 130H-Plus
Common/Usual Name: Vital Signs Monitoring Sensor
Classification Name: Monitor, Cardiac (Incl. Cardiotachometer & Rate Alarm) & Monitor, Breathing Frequency
Regulation Number: 21 CFR 870.2300 (Product Code DRT) & 21 CFR 868.2375 (Product Code BZQ)
Product Code: DRT & BZQ
Device Class: 2
Classification Panel: Cardiovascular

4. **Legally Marketed Predicate Device(s)**: Neteera's Vital Sign Monitoring Sensor Model: 130H (K212143)

5. **Indication for Use Statement**: The Neteera 130H-Plus device is intended for spot and continuous measurement of heart rate and respiration rate in adult patients (in healthcare facilities and home monitoring) and inform on bed exit.

The indications provided are to be used by health care professionals and are intended to be reviewed by clinicians to inform patient care.

The Neteera device is not intended to be used as an alarm system for potentially acute life-threatening situations in which medical intervention is necessary (e.g., ICU).

6. **Device Description**: Neteera 130H-Plus device is a modification of the predicate device Neteera 130H (K212143). It is a contact-free vital-signs monitor based on a high frequency (122.25-123 GHz) micro-radar on-chip and algorithm, capable of detecting Respiration Rate (RR) and Heart Rate (HR) during rest or subject's mild body movement, with the additional capability of identifying and notifying on bed exit.

   Neteera's micro- radar-based solution enables remote measurement, in real-time, in a non-invasive and contact-free manner. The system works by measuring only the ballistocardiograph micro-movements of the skin (BCG) through non-metallic materials such as furniture and clothing at a high resolution, and it has several different mounting options and measuring ranges.

7. **Performance Testing (Non-Clinical):**

   As part of demonstrating Substantial Equivalence for safety (electrical, EMC, etc.) and effectiveness of the Neteera 130H-Plus to the predicate device, Neteera Technologies Ltd. repeated several non-clinical performance (SW) and electrical safety tests that were performed for the predicate device. Testing results confirmed that the design output meets the design inputs and specifications of the subject device.

   Testing and/or compliance with the following standards has been achieved for the Neteera 130H-Plus Device:

   - IEC 60601-1-2: 2014 + A1: 2020 Edition 4.1Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests [tested as Class B, Group 2].
   - EN 60601-1-2:2015 + A1: 2021 Edition 4.1 - Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
   - IEC 60601-1-6:2010/AMDl:2013 for use in conjunction with IEC 62366:2007, AMD1:2014 and IEC 60601-1:2005, COR1:2006, COR2:2007, AMD1:2012 Medical electrical equipment - Part 1-6: General requirements for safety - Collateral standard: Usability.
   - EN 60601-1-6:2010/AMDl:2015 for use in conjunction with EN 60601-1:2006 + A11:2011 + A1:2013.
   - EN 60601-1-11:2015+A1:2021 Medical electrical equipment.
   - IEC 60601-1-11:2015+A1:2020 Medical electrical equipment - Part 1-11 for use in conjunction with IEC 60601-1:2005, AMD1:2012: General requirements for basic safety and essential performance - Collateral Standard: Requirements for

medical electrical equipment and medical electrical systems used in the home healthcare environment.

- EN 60601-1:2006 +A11:2011 + A1: 2013 Medical electrical equipment General requirements for basic safety and essential performance.
- IEC 60601-1:2005 AMD1: 2012 Medical electrical equipment General requirements for basic safety and essential performance.
- IEC 62366-1 Edition 1.0 2015-02 Medical devices - Part 1: Application of usability engineering to medical devices [Including CORRIGENDUM 1 (2016)]
- IEC 62304:2006/Al:2015 Medical device software - Software life cycle processes.
- AIM 7351731 Rev. 3.00 (2021-06-04) – Medical Electrical Equipment and System Electromagnetic Immunity Test for Exposure to Radio Frequency Identification Readers.
- IEEE/ANSI C63.27-2017– American National Standard for Evaluation of Wireless Coexistence.
- AAMI TIR69 2017 - Risk management of radio-frequency wireless coexistence for medical devices and systems.
- EN 305 550-1 V1.2.1 sections 7.1 thru 7.5, sec 8.1. Electromagnetic compatibility and Radio spectrum Matters (ERM); Short Range Devices (SRD); Radio equipment to be used in the 40 GHz to 246 GHz frequency range; Part 1: Technical characteristics and test methods.
- FCC 47 CFR part 15 (Operation in the bands 116-123 GHz) section 15.258(b), transmitter power test; section 15.215(c), occupied bandwidth; section 15.258(c) (2), Out of band radiated emissions below 40 GHz; section 15.258(c) (3), Out of band radiated emissions below 40 GHz up to 370 GHz; section 15.258(d), Frequency stability test; section 15.203, Antenna requirement.
- EN/IEC 60601-1-8 General requirements for safety – Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems

In addition to the testing above, software validation was also conducted. This validation demonstrated that the Neteera 130H-Plus performed and functioned as intended and according to the design specifications and as such is equivalent to the predicate.

8. **Clinical Testing**

As part of the validation of the effectiveness of the device, Neteera Technologies Ltd. completed a GCP-compliant confirmatory clinical validation study under Independent Ethical Committee approval to demonstrate that minor changes to the device did not affect clinical performance. The study compared the subject device to FDA-cleared devices in the same way and using the same FDA-cleared comparators as done for the clearance of the predicate device. Specifically, the comparators consisted of FDA-cleared devices ECG and Capnograph, EPM-10M S/N: AD1-03 for measuring Spot HR, Spot RR, Continuous HR and Continuous RR. Testing was performed on 46 subjects and all outcomes met the same pre-specified performance criteria.

9. **Statement of Substantial Equivalence**

The Neteera 130H-Plus device has the same intended use and same indications for use and technological characteristics as the predicate device, Neteera 130H, except it has the additional ability to detect and notify on Bed Exit of the monitored person, and minor hardware modifications were introduced.

The changes introduced for the 130H-Plus device and warranted this submission are hardware modification that required performance validation using human subjects and notification on Bed Exit which entails a change in the Intended Use (labeling).

The minor difference of having a feature that identifies and notifies on Bed Exit of the monitored subjects, and the hardware modifications do not raise different questions regarding the safety and effectiveness of the device. A Substantial Equivalence Table is presented below.

Therefore, based on the information provided in this 510(k) premarket notification, Neteera Technologies Ltd. concludes that the Neteera 130H-Plus device is substantially equivalent to the Neteera 130H predicate device.

Table 5A - Substantial Equivalence Chart for the Neteera 130H-Plus

	Subject Device	**Predicate Device**
510(K) Number	K231733	K212143
Device Name	Vital Sign Monitoring Sensor Neteera 130H-Plus	Vital Sign Monitoring Sensor Neteera 130H
Common name	Heart Rate and Respiratory Rate Monitor	Heart Rate and Respiratory Rate Monitor
Manufacturer	Neteera Technologies Ltd.	Neteera Technologies Ltd.
Intended Use	The Neteera System, Neteera 130H-Plus device, is intended for spot and continuous measurement of heart rate and respiration rate in adult patients (in healthcare facilities and home monitoring) and inform on bed exit. The indications provided are to be used by health care professionals and are intended	The Neteera System, Neteera 130/131H device, is intended for spot and continuous measurement of heart rate and respiration rate in adult patients (in healthcare facilities and home monitoring). The indications provided are to be used by health care professionals and are intended to

	to be reviewed by clinicians to inform patient care. The Neteera device is not intended to be used as an alarm system for potentially acute life-threatening situations in which medical intervention is necessary (e.g., ICU).	be reviewed by clinicians to inform patient care. The Neteera device is not intended to be used as an alarm system for potentially acute life-threatening situations in which medical intervention is necessary (e.g., ICU).
Components	Sensor; USB Cable, Power Supply	Sensor; USB Cable, Power Supply
Technology	Contactless, Radar-based measurement of micro-motions	Contactless, Radar-based measurement of micro-motions
Medical Parameters Monitored and Displayer	Heart Rate; Respiratory Rate, bed exit.	Heart Rate; Respiratory Rate
Patient Type	Adult	Adult
Use Environment	Healthcare facilities and home monitoring. The indications provided are to be used by health care professionals and are intended to be reviewed by clinicians to inform patient care. Not intended for potentially acute life-threatening situations.	Healthcare facilities and home monitoring. The indications provided are to be used by health care professionals and are intended to be reviewed by clinicians to inform patient care. Not intended for potentially acute life-threatening situations.
HR Measurement Range	40-160 Beats Per Minute	40-160 Beats per Minute
RR Measurement Range	5-40 Breaths Per Minute	5-40 Breaths per Minute
EMC Compliance	IEC 60601-1-2	IEC 60601-1-2
Product Electrical Safety and coexistence	IEC 60601-1; IEC 60601-1-6; IEC 60601-1-11 AIM 7351731 Rev. 3.00 IEEE/ANSI C63.27-2017 AAMI TIR69 2017 EN 305 550-1 V1.2.1 FCC 47 CFR part 15 EN/IEC 60601-1-8	IEC 60601-1; IEC 60601-1-6; IEC 60601-1-11 AIM 7351731 Rev. 3.00 IEEE/ANSI C63.27-2017 AAMI TIR69 2017 EN 305 550-1 V1.2.1 FCC 47 CFR part 15
Data Display	Cloud Dashboard	Cloud Dashboard