September 28, 2022

Neteera Technologies Ltd.
% Janice Hogan
Official Correspondent
Hogan Lovells US LLP
Hebrew University Givat Ram Campus,
High-tech Village - building 1.1/ P.O. Prof Rokah 2
Jerusalem, Jerusalem 9518702
Israel

Re: K212143
Trade/Device Name: Neteera 130H/131H 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: August 29, 2022
Received: August 29, 2022

Dear Janice Hogan:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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

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

Enclosure

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)*
K212143

Device Name
Neteera 130H/131H

Indications for Use *(Describe)*
The Neteera 130H/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 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.

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510(k) Summary

Device Name: Neteera 130H/131H
Vital Signs Monitoring Sensor

1. **510K Submission Sponsor**

   Neteera Technologies Ltd.

   High-Tech Village 1.1

   The Hebrew University of Jerusalem

   PO Box 39088

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   b. Rakefet Shohat, VP Quality and Regulations, Neteera Technologies Ltd.
      Email: rakefet.shohat@neteera.com

2. **Date Prepared**
   September 28, 2022

3. **Device Identification**
   Trade/Proprietary Name: Neteera 130H/131H
   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)**: Vital Sign Monitoring Sensor (Model: XK300), 510(k) K202464, manufactured by Xandar Kardian Inc.

5. **Indication for Use Statement**: The Neteera 130H/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 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/131H device 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 a variety of parameters: Respiration Rate (RR), Heart Rate (HR), during rest or subject's mild body movement.
   Neteera's micro radar-based solution enables measuring the micro-motions of the skin (BCG-Ballistocardiograph) remotely, in a real-time, non-invasive, and non-contact manner, through non-metallic materials such as furniture and clothing at a high resolution.

7. **Substantial Equivalence Discussion**

Table 5A – Comparison of Characteristics

	Subject Device	**Predicate Device**
510(K) Number	K212143	K202464
Device Name	Neteera 130H/131H	Vital Sign Monitoring Sensor (Model: XK300)
Common name	Heart Rate and Respiratory Rate Monitor	Heart Rate and Respiratory Rate Monitor
Manufacturer	Neteera Technologies Ltd.	Xandar Kardian Inc.
Intended Use	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 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).	The Vital Sign Monitoring Sensor (Model XK300) is intended to measure heart rate and respiration rate in adult patients in a general care hospital environment including nursing homes. The Vital Sign Monitoring Sensor can be used for home healthcare for data collection to inform patient care but not to acutely treat a patient. XK300 monitors presence or absence of a patient in a detection area of within 7 meters. The XK300 also monitors the length of continuous patient motion or absence of patient motion.
Components	Sensor; USB Cable, Power Supply	Sensor; USB Cable

Technology	Contactless, Radar-based measurement of micro-motions	Contactless, Radar-based measurement of micro-motions
Medical Parameters Monitored and Displayer	Heart Rate; Respiratory Rate	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.	General care hospital environment including nursing homes. The Vital Sign Monitoring Sensor can be used for home healthcare for data collection to inform patient care but not to acutely treat a patient.
HR Measurement Range	40 to 160 Beats Per Minute	55-130 Beats Per Minute
RR Measurement Range	5 to 40 Breaths Per Minute	5-60 Breaths Per Minute
EMC Compliance	IEC 60601-1-2	IEC 60601-1-2
Product Safety	IEC 60601-1; IEC 60601-1-6; IEC 60601-1-11	IEC 60601-1; IEC 60601-1-6; IEC 60601-1-11
Data Display	Cloud Dashboard and/or USB connection to display	Cloud Dashboard

8. Performance Testing (Non-Clinical)

As part of demonstrating safety and effectiveness of the device and in showing substantial equivalence to the predicate devices, Neteera Technologies Ltd. completed a number of non-clinical performance tests. The device meets all the requirements of the overall design. Testing results confirm that the design output meets the design inputs and specifications for the device.

The following testing has been performed using the Neteera 130H/131H Device:

- IEC 60601-1:2005/Al:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

- IEC 60601-1-2:2014 Medical 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]
- IEC 60601-1-6:2010/Al:2013 Medical electrical equipment - Part 1-6: General requirements for safety - Collateral standard: Usability
- IEC 60601-1-11:2015 Medical electrical equipment - Part 1-11: 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
- IEC 62366-1:2015 Medical devices - Part 1: Application of usability engineering to medical devices
- IEC 62304:2006/Al:2015 Medical device software - Software life cycle processes
- AIM 7351731 Rev. 2.00 (2017-02-23) – 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.

In addition to the testing above, software validation and usability testing were also conducted. This testing demonstrated that the Neteera 130H/131H performed and functioned as intended and according to the design specifications.

Performance testing evaluated the performance of the Neteera device in comparison with data generated by the following Reference Device:
MindRay Patient Monitor, model ePM 10M (K200015), manufactured by Shenzen Mindray Bio-Medical Electronics Co.

9. Clinical Testing

As part of demonstrating the safety and effectiveness of the device and in showing substantial equivalence to the predicate device, Neteera Technologies Ltd. completed a GCP-compliant clinical study with the device and FDA-cleared devices.

Clinical validation was performed in two parts:
- 100 subjects, Israel
- 70 Subjects, US population; specifically recruiting subjects with cardiopulmonary and metabolic medical disorders.

Performance Results of the overall ~170 Subjects mPP
Version 4.0

				SPOT			Continuous		
		HR	RR (*)	HR		RR	HR		RR
Parameter	Subgroup	Num. Setups HR	Num. Setups RR	under 10% error	5% or 5bpm Criteria	under 10% error or 2brpm	under 10% error	5% or 5bpm Criteria	under 10% error or 2brpm
Chair Back	Total	130	130	98.46	96.92%	96.15%	97.44%	95.96%	93.1%
Chair Front	Total	130	131	98.46%	96.92%	96.95%	98.7%	97.33%	93.52%
Above Bed	Part 2	34	34	97.06%	97.06%	91.18%	96.44%	95.28%	93.1%
All Front (Chair & Bed)		164	165	98.17%	96.95%	95.76%	98.26%	96.94%	93.44%

No safety issues were observed during the study.

Study population:

Subject demographics and baseline characteristics are shown below. The mean age of the study population was 43.20 ± 14.37 years (range, 18-76 years). Ninety subjects (52.94%) were females. The mean BMI was 28.46 ± 6.93 kg/cm2 (range, 16.40-50.50 years). On average the subjects participating in Part 2 were older with a higher BMI.

Subject baseline demographics

Parameter	Part 1 N=100	Part 2 N=70	Total N=170
Age (years)			
Mean ± SD	39.03 ± 12.66	49.14 ± 14.65	43.20 ± 14.37
Median (range)	39.5 (18-68)	48 (18-76)	42 (18-76)
Sex, n (%)			
Male	52 (52%)	28 (40%)	80 (47.06%)
Female	48 (48%)	42 (60%)	90 (52.94%)
Height, cm			
Mean ± SD	169.10 ± 9.56	168.73 ± 9.79	168.95 ± 9.63
Median (range)	169.15 (141-194)	168.75 (147-196.80)	168.80 (141-196.80)
Weight, kg			
Mean ± SD	75.15 ± 17.23	90.4 ± 23.65	81.43 ± 21.42
Median (range)	72 (40-130)	86.05 (53.70-152.40)	79 (40-152.40)
BMI, kg/cm2			
Mean ± SD	26.2 ± 5.32	31.68 ± 7.68	28.46 ± 6.93
Median (range)	25.24 (16.44-47.07)	29.45 (20.84-50.52)	26.70 (16.40-50.50)
BMI = body mass index, SD = standard deviation			

Source: NET-MED-002 CSR Post-Text Tables 14.1.2.1-14.1.2.5	

10. Conclusion

The device has the same intended use and similar indications for use and technological characteristics compared to the predicate device. The minor differences do not raise different questions regarding the safety and effectiveness of the device as compared to the predicate device. Therefore, based on the information provided in this 510(k) premarket notification, Neteera Technologies Ltd. concludes that the Neteera 130H/131H device is substantially equivalent to the Vital Signs Monitoring Sensor (Model: XK300; K202464) predicate device.