

K212143 Neteera 130H/131H Vital Sign Monitoring SensorSep 28, 2022
446 days to decisionK212143 · Product code: **DRT** · Cardiovascular
Source: <https://www.510kdatabase.net/k212143/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Cardiac (incl. Cardiotachometer & Rate Alarm) (DRT)
Date received	Jul 9, 2021
Decision date	Sep 28, 2022
Days to decision	446 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Neteera Technologies , Ltd.
Location	Jerusalem, IL
Contact	Yael Himmel
510(k) history	2 submissions · 2 cleared · 2022-2024

REGULATORY CONSULTANT

Consulting firm	Hogan Lovells US LLP
Contact	Janice M. Hogan

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

CLINICAL EVIDENCE - NCT04796181**Heart Rate and Respiratory Rate Measurements by a Novel, Radar-based Device**

Status	Completed - <i>No results published to ClinicalTrials.gov</i>
Enrollment	170 patients (actual)
Study sites	2 sites
Condition studied	Healthy Subjects; Chronic Conditions, Multiple
Study type	Observational
Completion date	Jul 2, 2022
Sponsor	Neteera Technologies Ltd. (Industry)

Primary outcome

Proportion of accurate spot HR while the Neteera 130H located behind the subject.

Secondary outcome

Repeating the primary endpoints in sitting position while the investigated device is located in front of the subject.

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT04796181