FDA 510(k) Premarket Notification

K221555 Dozee VS

CLEARED

Dec 15, 2022
198 days to decision

K221555 · Product code: **BZQ** · Anesthesiology
Source: https://www.510kdatabase.net/k221555/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Breathing Frequency (BZQ)
Date received	May 31, 2022
Decision date	Dec 15, 2022
Days to decision	198 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Turtle Shell Technologies Private Limited**
Location	Bengaluru, IN
Contact	Gaurav Parchani
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	**Hammond Clinical Trial Consulting, LLC**
Contact	David Hammond

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

CLINICAL EVIDENCE - NCT05153460

Pilot Clinical Evaluation of Dozee VS, a Contactless Continuous Vital Parameters Monitoring System in Hospital Patients

Status	Terminated - *No results published to ClinicalTrials.gov*
Enrollment	10 patients (actual)
Study sites	1 site
Condition studied	No Specific Medical Conditions or Disease States
Study type	Observational
Completion date	Apr 14, 2022
Sponsor	Turtle Shell Technologies Pvt. Ltd. (Industry)

Primary outcome

RMSD of Investigational Device's Heart Rate and Gold Standard Device's Heart Rate

Secondary outcome

Motion Notification Accuracy - DUI (%)

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT05153460

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k221555/ Data sourced from FDA 510(k) public records (accessdata.fda.gov), ClinicalTrials.gov (U.S. National Library of Medicine).
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