

K190775 The RHEA Vital Sign Vigilance SystemDec 19, 2019
268 days to decisionK190775 · Product code: **BZQ** · Anesthesiology
Source: <https://www.510kdatabase.net/k190775/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Breathing Frequency (BZQ)
Date received	Mar 26, 2019
Decision date	Dec 19, 2019
Days to decision	268 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Shenzhen Fiber Medical Technology Co. , Ltd.
Location	Shenzhen, CN
Contact	Luo Li
510(k) history	1 submissions · 1 cleared · 2019-2019

REGULATORY CONSULTANT

Consulting firm	Biologics Consulting Group
Contact	Donna-Bea Tillman

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

CLINICAL EVIDENCE - NCT03332147**Clinical Evaluation of the RHEA Vital Sign Vigilance System in Hospital Patients Patients**

Status	Completed - <i>No results published to ClinicalTrials.gov</i>
Enrollment	80 patients (actual)
Study sites	3 sites
Condition studied	Vital Sign Monitoring
Primary purpose	Screening
Study type	Interventional
Study design	Crossover
Masking	Open label
Completion date	Jun 30, 2018
Sponsor	Darma Inc. (Industry)

Primary outcome

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

Secondary outcome

Heart Rate t Test Comparison result between the Investigational Device and the Reference Device

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT03332147