

K243966 FaceHeart Vitals Software Development Kit (FH vitals SDK-RR)Apr 9, 2025
107 days to decisionK243966 · Product code: **BZQ** · Anesthesiology
Source: <https://www.510kdatabase.net/k243966/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Breathing Frequency (BZQ)
Date received	Dec 23, 2024
Decision date	Apr 9, 2025
Days to decision	107 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Faceheart Corp.
Location	Grand Cayman, KY
Contact	Dr. Meng Liang Chung
510(k) history	2 submissions · 2 cleared · 2023-2025

REGULATORY CONSULTANT

Consulting firm	Facehart Corp.
Contact	Dr. Meng Liang Chung

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k243966/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 14, 2026