FDA 510(k) Premarket Notification

CLEARED

K243966 FaceHeart Vitals Software Development Kit (FH vitals SDK-RR)

Apr 9, 2025
107 days to decision

K243966 · 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