

**K223622 FaceHeart Vitals Software Development Kit (FH vitals SDK)**Sep 1, 2023  
270 days to decisionK223622 · Product code: **QME** · Cardiovascular  
Source: <https://www.510kdatabase.net/k223622/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Software For Optical Camera-based Measurement Of Pulse Rate, Heart Rate, Breathing Rate, And/or Respiratory Rate (QME)
Date received	Dec 5, 2022
Decision date	Sep 1, 2023
Days to decision	270 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Faceheart Corp.</b>
Location	Grand Cayman, KY
Contact	Morris Chung
510(k) history	2 submissions · 2 cleared · 2023-2025

---

**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k223622/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 25, 2026