FDA 510(k) Premarket Notification

K232804 FibriCheck

CLEARED

Jun 7, 2024
269 days to decision

K232804 · Product code: **QME** · Cardiovascular
Source: https://www.510kdatabase.net/k232804/

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	Sep 12, 2023
Decision date	Jun 7, 2024
Days to decision	269 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Qompium NV**
Location	Hasselt, BE
Contact	Jo Van der Auwera
510(k) history	2 submissions · 2 cleared · 2018-2024

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k232804/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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