

K182344 RhythmAnalyticsMar 7, 2019
191 days to decisionK182344 · Product code: **DQK** · Cardiovascular
Source: <https://www.510kdatabase.net/k182344/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Computer, Diagnostic, Programmable (DQK)
Date received	Aug 28, 2018
Decision date	Mar 7, 2019
Days to decision	191 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Biofourmis Singapore Pte., Ltd.
Location	Singapore, SG
Contact	Kuldeep Singh Rajput
510(k) history	4 submissions · 4 cleared · 2019-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k182344/> 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 26, 2026