

K183282 Biovitals Analytics EngineAug 15, 2019
262 days to decisionK183282 · Product code: **PLB** · Cardiovascular
Source: <https://www.510kdatabase.net/k183282/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Multivariate Vital Signs Index (PLB)
Date received	Nov 26, 2018
Decision date	Aug 15, 2019
Days to decision	262 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/k183282/> 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