

**K233418 Biofourmis Everion+ (G2)**May 9, 2024  
212 days to decisionK233418 · Product code: **MSX** · CardiovascularSource: <https://www.510kdatabase.net/k233418/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Network And Communication, Physiological Monitors (MSX)
Date received	Oct 10, 2023
Decision date	May 9, 2024
Days to decision	212 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Biofourmis Singapore Pte., Ltd.</b>
Location	Singapore, SG
Contact	Seth Kuzdzal
510(k) history	4 submissions · 4 cleared · 2019-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k233418/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 14, 2026