FDA 510(k) Premarket Notification

K233418 Biofourmis Everion+ (G2)

CLEARED

May 9, 2024
212 days to decision

K233418 · Product code: **MSX** · Cardiovascular
Source: https://www.510kdatabase.net/k233418/

SUBMISSION DETAILS

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

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