FDA 510(k) Premarket Notification

K232354 Vios Monitoring System(TM) Model 2050

CLEARED

Mar 22, 2024
228 days to decision

K232354 · Product code: **DRT** · Cardiovascular
Source: https://www.510kdatabase.net/k232354/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Cardiac (incl. Cardiotachometer & Rate Alarm) (DRT)
Date received	Aug 7, 2023
Decision date	Mar 22, 2024
Days to decision	228 days
Third-party review	No
Summary / Statement	Summary
Other names	Vios Central Station Monitor/Vios Central Server Software

APPLICANT

Company	**Murata Vios, Inc.**
Location	Woodbury, MN, US
Contact	Amit Patel
510(k) history	2 submissions · 2 cleared · 2024-2025