FDA 510(k) Premarket Notification

K223812 Sensis Vibe (VD15)

CLEARED

Sep 15, 2023
269 days to decision

K223812 · Product code: **DQK** · Cardiovascular
Source: https://www.510kdatabase.net/k223812/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Computer, Diagnostic, Programmable (DQK)
Date received	Dec 20, 2022
Decision date	Sep 15, 2023
Days to decision	269 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Siemens Medical Solutions USA, Inc.**
Location	Hoffman Estates, IL, US
Contact	Patricia D Jones
510(k) history	778 submissions · 778 cleared · 1980-2026