FDA 510(k) Premarket Notification

CLEARED

K183128 EnSite Velocity Cardiac Mapping System v5.2, EnSite Precision Cardiac Mapping System v2.2

Dec 12, 2018
29 days to decision

K183128 · Product code: **DQK** · Cardiovascular
Source: https://www.510kdatabase.net/k183128/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Computer, Diagnostic, Programmable (DQK)
Date received	Nov 13, 2018
Decision date	Dec 12, 2018
Days to decision	29 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Abbott**
Location	St. Paul, MN, US
Contact	Cody Johnson
Website	http://www.abbott.com
510(k) history	12 submissions · 12 cleared · 2018-2026

Abbott is a global healthcare company developing life-changing medical devices and solutions. The company operates with a manufacturing facility in St. Paul, Minnesota. Abbott serves patients across multiple therapeutic areas including diabetes care, nutrition, diagnostics, and cardiovascular health. Abbott has received FDA 510(k) clearances from total submissions, with no denied submissions on record. The company's regulatory focus centers on Cardiovascular devices, which represent 91% of its FDA 510(k) portfolio. Abbott's first clearance was granted in 2018, with the mo...