

K201181 EnSite Velocity Cardiac Mapping System, EnSite Precision Cardiac Mapping System

Jun 26, 2020
57 days to decisionK201181 · Product code: **DQK** · Cardiovascular
Source: <https://www.510kdatabase.net/k201181/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Computer, Diagnostic, Programmable (DQK)
Date received	Apr 30, 2020
Decision date	Jun 26, 2020
Days to decision	57 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Abbott Medical
Location	S,Mta Clara, CA, US
Contact	Charlie Pickrell
Website	https://www.abbott.com
510(k) history	57 submissions · 57 cleared · 2019-2026

Abbott Medical is a global healthcare technology company headquartered in Santa Clara, US. The company specializes in life-changing medical devices and diagnostic solutions across multiple therapeutic areas. Abbott Medical maintains a strong FDA 510(k) regulatory record with FDA 510(k) clearances from total submissions. The company's primary focus is Cardiovascular devices, which represent 94% of its submission portfolio. Clearances span from 2019 to 2026, with recent activity demonstrating continued innovation in interventional cardiology and electrophysiology systems. R...

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Device record: <https://www.510kdatabase.net/k201181/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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