FDA 510(k) Premarket Notification

CLEARED

K201148 EnSite Precision Cardiac Mapping System v2.6, EnSite Precision Software Installation v2.6, EnSite LiveView Dynamic Display Software License

Jun 26, 2020
58 days to decision

K201148 · Product code: **DQK** · Cardiovascular
Source: https://www.510kdatabase.net/k201148/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Computer, Diagnostic, Programmable (DQK)
Date received	Apr 29, 2020
Decision date	Jun 26, 2020
Days to decision	58 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Abbott Medical**
Location	S,Mta Clara, CA, US
Contact	Alyssa Timmers
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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