FDA 510(k) Premarket Notification

K260212 EnSite™ X EP System

CLEARED

Apr 20, 2026
87 days to decision

K260212 · Product code: **DQK** · Cardiovascular
Source: https://www.510kdatabase.net/k260212/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Computer, Diagnostic, Programmable (DQK)
Date received	Jan 23, 2026
Decision date	Apr 20, 2026
Days to decision	87 days
Third-party review	No
Combination product	No
PCCP authorized	Yes - Predetermined Change Control Plan (AI/SaMD)
Summary / Statement	Summary

APPLICANT

Company	**Abbott Medical**
Location	S,Mta Clara, CA, US
Contact	Christine Kim
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/k260212/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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