

K231415 EnSite™ X EP SystemAug 10, 2023
86 days to decisionK231415 · Product code: **DQK** · Cardiovascular
Source: <https://www.510kdatabase.net/k231415/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Computer, Diagnostic, Programmable (DQK)
Date received	May 16, 2023
Decision date	Aug 10, 2023
Days to decision	86 days
Third-party review	No
Combination product	No
PCCP authorized	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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Device record: <https://www.510kdatabase.net/k231415/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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