

K251463 EnSite™ X EP System, AutoMark Index Software License (ENSITE-AMI-01)Sep 4, 2025
115 days to decisionK251463 · Product code: **DQK** · Cardiovascular
Source: <https://www.510kdatabase.net/k251463/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Computer, Diagnostic, Programmable (DQK)
Date received	May 12, 2025
Decision date	Sep 4, 2025
Days to decision	115 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	EnSite™ X EP System, AutoMark Index Temporary Software License (ENSITE-D-AMI-01)

APPLICANT

Company	Abbott Medical
Location	S,Mta Clara, CA, US
Contact	Alexandra Agre
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...