FDA 510(k) Premarket Notification

K212061 EnSite X EP System

CLEARED

Oct 22, 2021
113 days to decision

K212061 · Product code: **DQK** · Cardiovascular
Source: https://www.510kdatabase.net/k212061/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Computer, Diagnostic, Programmable (DQK)
Date received	Jul 1, 2021
Decision date	Oct 22, 2021
Days to decision	113 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Abbott**
Location	St. Paul, MN, US
Contact	Jamie Glaser
Website	http://www.abbott.com
510(k) history	12 submissions · 12 cleared · 2018-2026

Abbott is a global healthcare company developing life-changing medical devices and solutions. The company operates with a manufacturing facility in St. Paul, Minnesota. Abbott serves patients across multiple therapeutic areas including diabetes care, nutrition, diagnostics, and cardiovascular health. Abbott has received FDA 510(k) clearances from total submissions, with no denied submissions on record. The company's regulatory focus centers on Cardiovascular devices, which represent 91% of its FDA 510(k) portfolio. Abbott's first clearance was granted in 2018, with the mo...