CLEARED

Nov 25, 2020
121 days to decision

K202066 EnSite X EP System, Advisor VL Circular Mapping Catheter, Sensor Enabled, Advisor FL Circular Mapping Catheter, Sensor Enabled, Advisor HD Grid High Density Mapping Catheter, Senor Enabled

K202066 · Product code: **DQK** · Cardiovascular
Source: https://www.510kdatabase.net/k202066/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Computer, Diagnostic, Programmable (DQK)
Date received	Jul 27, 2020
Decision date	Nov 25, 2020
Days to decision	121 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...