FDA 510(k) Premarket Notification

CLEARED

K230286 Assert-IQ™ Insertable Cardiac Monitor

May 17, 2023
104 days to decision

K230286 · Product code: **MXC** · Cardiovascular
Source: https://www.510kdatabase.net/k230286/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Recorder, Event, Implantable Cardiac, (without Arrhythmia Detection) (MXC)
Date received	Feb 2, 2023
Decision date	May 17, 2023
Days to decision	104 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	Laura Sparks
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...

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k230286/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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