

**K253516 Assert-IQ (DM5100)**Dec 18, 2025  
36 days to decisionK253516 · Product code: **MXD** · Cardiovascular  
Source: <https://www.510kdatabase.net/k253516/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Recorder, Event, Implantable Cardiac, (with Arrhythmia Detection) (MXD)
Date received	Nov 12, 2025
Decision date	Dec 18, 2025
Days to decision	36 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Abbott Medical</b>
Location	S,Mta Clara, CA, US
Contact	Komal Panchal
Website	<a href="https://www.abbott.com">https://www.abbott.com</a>
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...