

**K260499 Amplatzer™ Trevisio™ Intravascular Delivery System**Mar 13, 2026  
28 days to decisionK260499 · Product code: **DQY** · Cardiovascular  
Source: <https://www.510kdatabase.net/k260499/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Percutaneous (DQY)
Date received	Feb 13, 2026
Decision date	Mar 13, 2026
Days to decision	28 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	9-ATV06F45/609-ATV07F45/609-ATV07F45/809-ATV08F45/609-ATV08F45/ 809-ATV09F45/809-ATV10F45/809-ATV12F45/80

**APPLICANT**

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Company	<b>Abbott Medical</b>
Location	S,Mta Clara, CA, US
Contact	Meghann Kayoum
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...