FDA 510(k) Premarket Notification

CLEARED

K261825 Amplatzer TorqVue LP Delivery System

Jul 2, 2026
30 days to decision

K261825 · Product code: **DQY** · Cardiovascular
Source: https://www.510kdatabase.net/k261825/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Percutaneous (DQY)
Date received	Jun 2, 2026
Decision date	Jul 2, 2026
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary
Other names	Amplatzer TorqVue LP Catheter

APPLICANT

Company	**Abbott**
Location	St. Paul, MN, US
Contact	Maddie Cook
Website	http://www.abbott.com
510(k) history	13 submissions · 13 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...