FDA 510(k) Premarket Notification

CLEARED

K243224 MitraClip™ G5 Steerable Guide Catheter (SGC0801)

Dec 31, 2024
85 days to decision

K243224 · Product code: **DQY** · Cardiovascular
Source: https://www.510kdatabase.net/k243224/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous (DQY)
Date received	Oct 7, 2024
Decision date	Dec 31, 2024
Days to decision	85 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	TriClip™ G5 Steerable Guide Catheter (TSGC0801)

APPLICANT

Company	**Abbott Medical**
Location	S,Mta Clara, CA, US
Contact	Vidya Thyagarajan
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...