

K250558 SelectSite C304 Deflectable Catheter System (C304)Mar 27, 2025
30 days to decisionK250558 · Product code: **DQY** · Cardiovascular
Source: <https://www.510kdatabase.net/k250558/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Percutaneous (DQY)
Date received	Feb 25, 2025
Decision date	Mar 27, 2025
Days to decision	30 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	C315 Delivery System (C315)

APPLICANT

Company	Medtronic, Inc.
Location	Mounds View, MN, US
Contact	Samiksha Tiwari
Website	https://www.medtronic.com
510(k) history	209 submissions · 208 cleared · 1981-2026

Medtronic, Inc. is a global medical device manufacturer headquartered in Mounds View, United States. The company develops and markets a broad range of medical devices across multiple therapeutic areas. Medtronic maintains a strong FDA 510(k) regulatory track record with FDA 510(k) cleared devices from total submissions since 1981. The company specializes primarily in Cardiovascular devices, which represent 82% of its submission portfolio. Recent clearances include coronary perfusion cannulae, intracoronary shunts, venous cannulae, guidewires, deflectable catheter systems,...