

K223178 SelectSite C304 Deflectable Catheter System, C315 Delivery System

Nov 8, 2022
28 days to decisionK223178 · Product code: **DQY** · Cardiovascular
Source: <https://www.510kdatabase.net/k223178/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Percutaneous (DQY)
Date received	Oct 11, 2022
Decision date	Nov 8, 2022
Days to decision	28 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Medtronic
Location	Minneapolis, MN, US
Contact	Sarah Meyer
Website	http://www.medtronic.com/us-en/index.html
510(k) history	32 submissions · 32 cleared · 2007-2026

Medtronic is an American-Irish medical device company with operational headquarters in Minneapolis, Minnesota. The company operates globally across more than 150 countries and is the largest medical device company in the world by revenue. Medtronic has received FDA 510(k) clearances from total submissions since 2007. The company's regulatory portfolio is dominated by cardiovascular devices, including oxygenation systems, arterial filters, cardioplegia delivery systems, and catheter-based interventions. Medtronic also maintains a significant presence in orthopedic spinal s...