

K161287 DxTerity, DxTerity TRA, DxTerity Angio-Kit, DxTerity EZ-Pak, DxTerity TRA Angio-Kit, DxTerity TRA EZ-PakAug 19, 2016
102 days to decisionK161287 · Product code: **DQO** · Cardiovascular
Source: <https://www.510kdatabase.net/k161287/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent - K
Submission type	Traditional
Device classification	Catheter, Intravascular, Diagnostic (DQO)
Date received	May 9, 2016
Decision date	Aug 19, 2016
Days to decision	102 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Medtronic Vascular
Location	Walker, MI, US
Contact	Nisarg Shah
510(k) history	475 submissions · 453 cleared · 1977-2023

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k161287/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 14, 2026