

K181001 Medtronic Confida Brecker GuidewireMay 3, 2018
17 days to decisionK181001 · Product code: **DQX** · CardiovascularSource: <https://www.510kdatabase.net/k181001/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wire, Guide, Catheter (DQX)
Date received	Apr 16, 2018
Decision date	May 3, 2018
Days to decision	17 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	Medtronic Core Valve, LLC
Location	Santa Rosa, CA, US
Contact	Gerardine Drummond
510(k) history	2 submissions · 2 cleared · 2015-2018

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k181001/> 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