

K132623 MEDTRONIC CONFIDA BRECKER CURVE GUIDEWIREDec 19, 2013
119 days to decisionK132623 · Product code: **DQX** · Cardiovascular
Source: <https://www.510kdatabase.net/k132623/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wire, Guide, Catheter (DQX)
Date received	Aug 22, 2013
Decision date	Dec 19, 2013
Days to decision	119 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Medtronic
Location	Minneapolis, MN, US
Contact	MONICA HERNANDEZ-SOTO
Website	http://www.medtronic.com/us-en/index.html
510(k) history	33 submissions · 33 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...
