FDA 510(k) Premarket Notification

# K181001 Medtronic Confida Brecker Guidewire

**CLEARED**

May 3, 2018
17 days to decision

K181001 · Product code: **DQX** · Cardiovascular
Source: 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 |