CLEARED

K163233 MIVI 6F 25cm Mi-EXT Extension Catheter, MIVI 5F 25cm Mi-EXT Extension Catheter, MIVI 4F 30cm Mi-EXT Extension Catheter, MIVI 3F 43cm Mi-EXT Extension Catheter

Apr 6, 2017
140 days to decision

K163233 · Product code: **DQY** · Cardiovascular
Source: https://www.510kdatabase.net/k163233/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous (DQY)
Date received	Nov 17, 2016
Decision date	Apr 6, 2017
Days to decision	140 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Mivi Neuroscience, Inc.**
Location	Eden Prarie, MN, US
Contact	Randy LaBounty
510(k) history	5 submissions · 5 cleared · 2015-2023