FDA 510(k) Premarket Notification

K151396 MIVI Mi-AXUS Guide Catheter

CLEARED

Dec 9, 2015
197 days to decision

K151396 · Product code: **DQY** · Cardiovascular
Source: https://www.510kdatabase.net/k151396/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous (DQY)
Date received	May 26, 2015
Decision date	Dec 9, 2015
Days to decision	197 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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