FDA 510(k) Premarket Notification

K171557 AcQRef Introducer Sheath

CLEARED

Feb 6, 2018
252 days to decision

K171557 · Product code: **DYB** · Cardiovascular
Source: https://www.510kdatabase.net/k171557/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	May 30, 2017
Decision date	Feb 6, 2018
Days to decision	252 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Acutus Medical, Inc.**
Location	Carlsbad, CA, US
Contact	Brenda Clay
510(k) history	24 submissions · 24 cleared · 2017-2023