FDA 510(k) Premarket Notification

K172790 ER-REBOA Catheter

CLEARED

Nov 8, 2017
54 days to decision

K172790 · Product code: **MJN** · Cardiovascular
Source: https://www.510kdatabase.net/k172790/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Intravascular Occluding, Temporary (MJN)
Date received	Sep 15, 2017
Decision date	Nov 8, 2017
Days to decision	54 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Prytime Medical Devices, Inc.**
Location	Boerne, TX, US
Contact	Brian Young
510(k) history	5 submissions · 5 cleared · 2017-2025