FDA 510(k) Premarket Notification

K183679 Occlusion Balloon Catheter

CLEARED

Apr 24, 2019
117 days to decision

K183679 · Product code: **MJN** · Cardiovascular
Source: https://www.510kdatabase.net/k183679/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Intravascular Occluding, Temporary (MJN)
Date received	Dec 28, 2018
Decision date	Apr 24, 2019
Days to decision	117 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Qxmedical, LLC**
Location	St. Paul, MN, US
Contact	Fernando Di Caprio
510(k) history	5 submissions · 5 cleared · 2012-2020