FDA 510(k) Premarket Notification

K183357 XableCath Crossing Catheter

CLEARED

Jan 21, 2019
48 days to decision

K183357 · Product code: **PDU** · Cardiovascular
Source: https://www.510kdatabase.net/k183357/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter For Crossing Total Occlusions (PDU)
Date received	Dec 4, 2018
Decision date	Jan 21, 2019
Days to decision	48 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Xablecath, Inc.**
Location	Salt Lake City, UT, US
Contact	Rick Gaykowski
510(k) history	3 submissions · 3 cleared · 2017-2019