FDA 510(k) Premarket Notification

K182360 Teleport Microcatheter

CLEARED

Nov 9, 2018
71 days to decision

K182360 · Product code: **DQY** · Cardiovascular
Source: https://www.510kdatabase.net/k182360/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous (DQY)
Date received	Aug 30, 2018
Decision date	Nov 9, 2018
Days to decision	71 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Orbusneich Medical Trading, Inc.**
Location	Fort Lauderdale, FL, US
Contact	John Pazienza
510(k) history	7 submissions · 7 cleared · 2018-2020