FDA 510(k) Premarket Notification

K183000 ViperCath XC Peripheral Exchange Catheter

CLEARED

Dec 29, 2018
60 days to decision

K183000 · Product code: **DQY** · Cardiovascular
Source: https://www.510kdatabase.net/k183000/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous (DQY)
Date received	Oct 30, 2018
Decision date	Dec 29, 2018
Days to decision	60 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Cardiovascular Systems, Inc.**
Location	Saint Paul, MN, US
Contact	Erika Huffman
510(k) history	26 submissions · 26 cleared · 2007-2022