FDA 510(k) Premarket Notification

K192625 PG Pro Microcatheter

CLEARED

Nov 21, 2019
59 days to decision

K192625 · Product code: **DQY** · Cardiovascular
Source: https://www.510kdatabase.net/k192625/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous (DQY)
Date received	Sep 23, 2019
Decision date	Nov 21, 2019
Days to decision	59 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**MicroVention, Inc. A TERUMO Group Company**
Location	Aliso Veijo, CA, US
Contact	Ganesh Balachandar
510(k) history	1 submissions · 1 cleared · 2019-2019