FDA 510(k) Premarket Notification

K171176 M-CATH Microcatheter

CLEARED

Sep 15, 2017
147 days to decision

K171176 · Product code: **DQY** · Cardiovascular
Source: https://www.510kdatabase.net/k171176/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous (DQY)
Date received	Apr 21, 2017
Decision date	Sep 15, 2017
Days to decision	147 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Acrostak (Schweiz) AG**
Location	Winterthur, CH
Contact	Carmen Herraez
510(k) history	1 submissions · 1 cleared · 2017-2017