FDA 510(k) Premarket Notification

K180286 Polyethylene Catheter

CLEARED

Oct 26, 2018
267 days to decision

K180286 · Product code: **DQO** · Cardiovascular
Source: https://www.510kdatabase.net/k180286/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Intravascular, Diagnostic (DQO)
Date received	Feb 1, 2018
Decision date	Oct 26, 2018
Days to decision	267 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Cook Incorporated**
Location	Bloomington, IN, US
Contact	Jessica Swafford
510(k) history	175 submissions · 153 cleared · 2006-2024