FDA 510(k) Premarket Notification

K181722 Polyethylene Catheter

CLEARED

Mar 22, 2019
266 days to decision

K181722 · Product code: **DQO** · Cardiovascular
Source: https://www.510kdatabase.net/k181722/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Intravascular, Diagnostic (DQO)
Date received	Jun 29, 2018
Decision date	Mar 22, 2019
Days to decision	266 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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