FDA 510(k) Premarket Notification

K183036 Dilator Sets

CLEARED

Dec 20, 2018
49 days to decision

K183036 · Product code: **DRE** · Cardiovascular
Source: https://www.510kdatabase.net/k183036/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dilator, Vessel, For Percutaneous Catheterization (DRE)
Date received	Nov 1, 2018
Decision date	Dec 20, 2018
Days to decision	49 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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