FDA 510(k) Premarket Notification

K191163 Lumax Guiding Catheter

CLEARED

Dec 12, 2019
225 days to decision

K191163 · Product code: **DQY** · Cardiovascular
Source: https://www.510kdatabase.net/k191163/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous (DQY)
Date received	May 1, 2019
Decision date	Dec 12, 2019
Days to decision	225 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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