FDA 510(k) Premarket Notification

CLEARED

K183632 Diagnostic Fixed Electrophysiology Lumen Catheter , Diagnostic Electrophysiology Cable

Jun 7, 2019
163 days to decision

K183632 · Product code: **DRF** · Cardiovascular
Source: https://www.510kdatabase.net/k183632/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Electrode Recording, Or Probe, Electrode Recording (DRF)
Date received	Dec 26, 2018
Decision date	Jun 7, 2019
Days to decision	163 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Baylis Medical Company, Inc.**
Location	Mississauga, Ontario, CA
Contact	Meghal Khakhar
510(k) history	24 submissions · 24 cleared · 2012-2025