

**K183649 Diagnostic Fixed Electrophysiology Catheter,  
Diagnostic Electrophysiology Cable**

Jun 7, 2019  
163 days to decision

K183649 · Product code: DRF · Cardiovascular  
Source: <https://www.510kdatabase.net/k183649/>

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k183649/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 14, 2026