

K192774 BioCardia 8F Morph DNA Deflectable Guide CatheterJan 7, 2020
99 days to decisionK192774 · Product code: **DQY** · CardiovascularSource: <https://www.510kdatabase.net/k192774/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Percutaneous (DQY)
Date received	Sep 30, 2019
Decision date	Jan 7, 2020
Days to decision	99 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Biocardia
Location	San Carlos, CA, US
Contact	Patrick Lee
510(k) history	2 submissions · 2 cleared · 2020-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k192774/> 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 26, 2026