

**K012749 BIOCARDIA UNIVERSAL DEFLECTABLE GUIDE  
CATHETER, MODEL 000664**Jan 24, 2002  
161 days to decisionK012749 · Product code: **DQO** · Cardiovascular  
Source: <https://www.510kdatabase.net/k012749/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Intravascular, Diagnostic (DQO)
Date received	Aug 16, 2001
Decision date	Jan 24, 2002
Days to decision	161 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Biocardia, Inc.</b>
Location	South San Francisco, CA, US
Contact	DANIEL C ROSENMAN
510(k) history	4 submissions · 4 cleared · 2002-2019

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k012749/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 23, 2026