

**K062126 EMBOCATH PLUS INFUSION MICROCATHETER,  
MODEL ECP-100 AND ECP-135**Aug 9, 2006  
14 days to decisionK062126 · Product code: **DQO** · Cardiovascular  
Source: <https://www.510kdatabase.net/k062126/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Intravascular, Diagnostic (DQO)
Date received	Jul 26, 2006
Decision date	Aug 9, 2006
Days to decision	14 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Biosphere Medical, Inc.</b>
Location	Rockland, MA, US
Contact	IRINA KULINETS
510(k) history	6 submissions · 6 cleared · 2001-2012

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k062126/> 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 15, 2026