

**K003105 BIOSPHERE MEDICAL INFUSION CATHETER**May 22, 2001  
230 days to decisionK003105 · Product code: **DQO** · Cardiovascular  
Source: <https://www.510kdatabase.net/k003105/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Intravascular, Diagnostic (DQO)
Date received	Oct 4, 2000
Decision date	May 22, 2001
Days to decision	230 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Biosphere Medical</b>
Location	Rockland, MA, US
Contact	JOHN BONASERA
510(k) history	2 submissions · 2 cleared · 2000-2001

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k003105/> 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 30, 2026