

**K982232 MODIFICATION OF THE IBI-1100 STEERABLE  
ELECTROPHYSIOLOGY CATHETER SYSTEM**Jul 25, 1998  
30 days to decisionK982232 · Product code: DRF · Cardiovascular  
Source: <https://www.510kdatabase.net/k982232/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Electrode Recording, Or Probe, Electrode Recording (DRF)
Date received	Jun 25, 1998
Decision date	Jul 25, 1998
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Irvine Biomedical, Inc.</b>
Location	Irvine, CA, US
Contact	ROGER TU
510(k) history	11 submissions · 11 cleared · 1995-2008

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k982232/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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