

**K042775 INQUIRY AFOCUS, INQUIRY AFOCUS II AND INQUIRY
OPTIMA STEERABLE ELECTROPHYSIOLOGY CATHETER**Nov 4, 2004
29 days to decisionK042775 · Product code: DRF · Cardiovascular
Source: <https://www.510kdatabase.net/k042775/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Electrode Recording, Or Probe, Electrode Recording (DRF)
Date received	Oct 6, 2004
Decision date	Nov 4, 2004
Days to decision	29 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Irvine Biomedical, Inc.
Location	Irvine, CA, US
Contact	BONNIE BISHOP
510(k) history	11 submissions · 11 cleared · 1995-2008

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k042775/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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