

**K010471 AFOCUS ELECTROPHYSIOLOGY CATHETER SYSTEM,
MODELS 81550, 81567, 81568, 81569**Jun 6, 2001
106 days to decisionK010471 · Product code: DRF · Cardiovascular
Source: <https://www.510kdatabase.net/k010471/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Electrode Recording, Or Probe, Electrode Recording (DRF)
Date received	Feb 20, 2001
Decision date	Jun 6, 2001
Days to decision	106 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k010471/> Data sourced from FDA 510(k) public records (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. - Generated June 24, 2026