

**K060757 INQUIRY OPTIMA PLUS STEERABLE
ELECTROPHYSIOLOGY CATHETER**Apr 19, 2006
29 days to decisionK060757 · Product code: DRF · Cardiovascular
Source: <https://www.510kdatabase.net/k060757/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Electrode Recording, Or Probe, Electrode Recording (DRF)
Date received	Mar 21, 2006
Decision date	Apr 19, 2006
Days to decision	29 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k060757/>; 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