

**K961924 IBI-1100 STEERABLE ELECTROPHYSIOLOGY
CATHETER SYSTEM**Apr 11, 1997
329 days to decisionK961924 · Product code: **DRF** · Cardiovascular
Source: <https://www.510kdatabase.net/k961924/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Electrode Recording, Or Probe, Electrode Recording (DRF)
Date received	May 17, 1996
Decision date	Apr 11, 1997
Days to decision	329 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k961924/> 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