

K946333 IBI-1000(TM) ELECTROPHYSIOLOGY CATHETERJul 18, 1995
201 days to decisionK946333 · Product code: **DRF** · Cardiovascular
Source: <https://www.510kdatabase.net/k946333/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Electrode Recording, Or Probe, Electrode Recording (DRF)
Date received	Dec 29, 1994
Decision date	Jul 18, 1995
Days to decision	201 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

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