

K991878 LUMA-CATH STEERABLE EP CATHETERSDec 10, 1999
191 days to decisionK991878 · Product code: **DRF** · Cardiovascular
Source: <https://www.510kdatabase.net/k991878/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Electrode Recording, Or Probe, Electrode Recording (DRF)
Date received	Jun 2, 1999
Decision date	Dec 10, 1999
Days to decision	191 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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