

K053582 INQUIRY AFOCUS II DIAGNOSTIC CATHETERMar 21, 2006
88 days to decisionK053582 · Product code: **DRF** · CardiovascularSource: <https://www.510kdatabase.net/k053582/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Electrode Recording, Or Probe, Electrode Recording (DRF)
Date received	Dec 23, 2005
Decision date	Mar 21, 2006
Days to decision	88 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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