FDA 510(k) Premarket Notification

K082061 INQUIRY H-CURVE TV STEERABLE DIAGNOSTIC CATHETER

CLEARED

Aug 19, 2008
29 days to decision

K082061 · Product code: **DRF** · Cardiovascular
Source: https://www.510kdatabase.net/k082061/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Electrode Recording, Or Probe, Electrode Recording (DRF)
Date received	Jul 21, 2008
Decision date	Aug 19, 2008
Days to decision	29 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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