FDA 510(k) Premarket Notification

CLEARED

K982232 MODIFICATION OF THE IBI-1100 STEERABLE ELECTROPHYSIOLOGY CATHETER SYSTEM

Jul 25, 1998
30 days to decision

K982232 · Product code: **DRF** · Cardiovascular
Source: https://www.510kdatabase.net/k982232/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Electrode Recording, Or Probe, Electrode Recording (DRF)
Date received	Jun 25, 1998
Decision date	Jul 25, 1998
Days to decision	30 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