FDA 510(k) Premarket Notification

K961924 IBI-1100 STEERABLE ELECTROPHYSIOLOGY CATHETER SYSTEM

CLEARED

Apr 11, 1997
329 days to decision

K961924 · Product code: **DRF** · Cardiovascular
Source: https://www.510kdatabase.net/k961924/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Electrode Recording, Or Probe, Electrode Recording (DRF)
Date received	May 17, 1996
Decision date	Apr 11, 1997
Days to decision	329 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