FDA 510(k) Premarket Notification

K960542 NOGA

CLEARED

Apr 15, 1996
68 days to decision

K960542 · Product code: **DRF** · Cardiovascular
Source: https://www.510kdatabase.net/k960542/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Electrode Recording, Or Probe, Electrode Recording (DRF)
Date received	Feb 7, 1996
Decision date	Apr 15, 1996
Days to decision	68 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Biosense, Ltd.**
Location	Tirat Hacarmel, IL
Contact	SUSAN J ZACHMAN
510(k) history	3 submissions · 3 cleared · 1995-1998