FDA 510(k) Premarket Notification

K926549 ENDOCATH ELECTROPHYSIOLOGY CATHETER

CLEARED

Dec 6, 1993
340 days to decision

K926549 · Product code: **DRF** · Cardiovascular
Source: https://www.510kdatabase.net/k926549/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Electrode Recording, Or Probe, Electrode Recording (DRF)
Date received	Dec 31, 1992
Decision date	Dec 6, 1993
Days to decision	340 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Endo-Therapeutics, Inc.**
Location	Safety Harbor, FL, US
Contact	JEFFREY R BUDD
510(k) history	7 submissions · 7 cleared · 1993-2009