FDA 510(k) Premarket Notification

K853747 NAVIGATOR

CLEARED

Jan 8, 1986
121 days to decision

K853747 · Product code: **DTB** · Cardiovascular
Source: https://www.510kdatabase.net/k853747/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Permanent Pacemaker Electrode (DTB)
Date received	Sep 9, 1985
Decision date	Jan 8, 1986
Days to decision	121 days
Third-party review	No

APPLICANT

Company	**Mainsfield Scientific, Inc.**
Location	Mansfield, MA, US
Contact	BRUCE BEAUCHEMIN
510(k) history	1 submissions · 1 cleared · 1986-1986