FDA 510(k) Premarket Notification

K905300 PERMANENT PACING LEAD

CLEARED

May 7, 1991
161 days to decision

K905300 · Product code: **DTB** · Cardiovascular
Source: https://www.510kdatabase.net/k905300/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Permanent Pacemaker Electrode (DTB)
Date received	Nov 27, 1990
Decision date	May 7, 1991
Days to decision	161 days
Third-party review	No

APPLICANT

Company	**Oscor Medical Corp.**
Location	Washington, DC, US
Contact	RONALD NIEUWENENHOF
510(k) history	31 submissions · 30 cleared · 1985-1997