FDA 510(k) Premarket Notification

K913204 MODEL KY PACEMAKER LEAD-VARIOUS, MODIFICATION

CLEARED

Sep 23, 1991
77 days to decision

K913204 · Product code: **DTB** · Cardiovascular
Source: https://www.510kdatabase.net/k913204/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Permanent Pacemaker Electrode (DTB)
Date received	Jul 8, 1991
Decision date	Sep 23, 1991
Days to decision	77 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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