FDA 510(k) Premarket Notification

K823895 MODEL RF. D&RX..D PACEMAKER LEADS

CLEARED

Apr 30, 1983
124 days to decision

K823895 · Product code: **DTB** · Cardiovascular
Source: https://www.510kdatabase.net/k823895/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Permanent Pacemaker Electrode (DTB)
Date received	Dec 27, 1982
Decision date	Apr 30, 1983
Days to decision	124 days
Third-party review	No

APPLICANT

Company	**Oscor, Inc.**
Location	Palm Harbor, FL, US
510(k) history	49 submissions · 46 cleared · 1979-2021