FDA 510(k) Premarket Notification

K823891 MODEL KY PACEMAKER LEAD - VARIOUS

CLEARED

Mar 31, 1983
94 days to decision

K823891 · Product code: **DTB** · Cardiovascular
Source: https://www.510kdatabase.net/k823891/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Permanent Pacemaker Electrode (DTB)
Date received	Dec 27, 1982
Decision date	Mar 31, 1983
Days to decision	94 days
Third-party review	No

APPLICANT

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