FDA 510(k) Premarket Notification

K923621 EXTERNAL DEMAND PACEMAKER

CLEARED

May 19, 1993
302 days to decision

K923621 · Product code: **DTE** · Cardiovascular
Source: https://www.510kdatabase.net/k923621/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pulse-generator, Pacemaker, External (DTE)
Date received	Jul 21, 1992
Decision date	May 19, 1993
Days to decision	302 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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