FDA 510(k) Premarket Notification

K831768 EXTERNAL PULSE GENERATOR FOR TEMP. STIM

CLEARED

Dec 16, 1983
198 days to decision

K831768 · Product code: **DTE** · Cardiovascular
Source: https://www.510kdatabase.net/k831768/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pulse-generator, Pacemaker, External (DTE)
Date received	Jun 1, 1983
Decision date	Dec 16, 1983
Days to decision	198 days
Third-party review	No

APPLICANT

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