FDA 510(k) Premarket Notification

K961118 MAXIM PF MODELS 033-581/033-590

CLEARED

Jul 15, 1996
117 days to decision

K961118 · Product code: **DTB** · Cardiovascular
Source: https://www.510kdatabase.net/k961118/

SUBMISSION DETAILS

Decision	Substantially Equivalent - ST
Submission type	Traditional
Device classification	Permanent Pacemaker Electrode (DTB)
Date received	Mar 20, 1996
Decision date	Jul 15, 1996
Days to decision	117 days
Third-party review	No

APPLICANT

Company	**Telectronics Pacing Systems, Inc.**
Location	Englewood, CO, US
Contact	ANDREW CLEELAND
510(k) history	20 submissions · 18 cleared · 1989-1996