FDA 510(k) Premarket Notification

K832255 MODEL F UNIPOLAR ENDOCARDIAL LEAD-

CLEARED

Aug 12, 1983
32 days to decision

K832255 · Product code: **DTB** · Cardiovascular
Source: https://www.510kdatabase.net/k832255/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Permanent Pacemaker Electrode (DTB)
Date received	Jul 11, 1983
Decision date	Aug 12, 1983
Days to decision	32 days
Third-party review	No

APPLICANT

Company	**Cook Pacemaker Corp.**
Location	Mchenry, IL, US
510(k) history	34 submissions · 31 cleared · 1981-1997