FDA 510(k) Premarket Notification

K811876 MODEL D BIPOLAR ENDOCARDIAL LEAD

CLEARED

Aug 3, 1981
33 days to decision

K811876 · Product code: **DTB** · Cardiovascular
Source: https://www.510kdatabase.net/k811876/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Permanent Pacemaker Electrode (DTB)
Date received	Jul 1, 1981
Decision date	Aug 3, 1981
Days to decision	33 days
Third-party review	No

APPLICANT

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