FDA 510(k) Premarket Notification

K800782 PACE-PULSE/COMPUTRAC

CLEARED

May 28, 1980
50 days to decision

K800782 · Product code: **KRE** · Cardiovascular
Source: https://www.510kdatabase.net/k800782/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Analyzer, Pacemaker Generator Function, Indirect (KRE)
Date received	Apr 8, 1980
Decision date	May 28, 1980
Days to decision	50 days
Third-party review	No

APPLICANT

Company	**Bib, Inc.**
Location	Mchenry, IL, US
510(k) history	5 submissions · 5 cleared · 1980-1983