FDA 510(k) Premarket Notification

K801022 ULTRA-CHEK PACEMAKER MONITOR

CLEARED

Jun 17, 1980
48 days to decision

K801022 · Product code: **KRE** · Cardiovascular
Source: https://www.510kdatabase.net/k801022/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Analyzer, Pacemaker Generator Function, Indirect (KRE)
Date received	Apr 30, 1980
Decision date	Jun 17, 1980
Days to decision	48 days
Third-party review	No

APPLICANT

Company	**Powers Medical Systmes**
Location	Walker, MI, US
510(k) history	3 submissions · 3 cleared · 1980-1981