FDA 510(k) Premarket Notification

K801596 CYNERGY MODEL 184

CLEARED

Sep 16, 1980
64 days to decision

K801596 · Product code: **DTE** · Cardiovascular
Source: https://www.510kdatabase.net/k801596/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pulse-generator, Pacemaker, External (DTE)
Date received	Jul 14, 1980
Decision date	Sep 16, 1980
Days to decision	64 days
Third-party review	No

APPLICANT

Company	**Cynergy**
Location	Mchenry, IL, US
510(k) history	5 submissions · 5 cleared · 1978-1981