FDA 510(k) Premarket Notification

K923398 CPI MODEL 2215

CLEARED

Aug 14, 1992
35 days to decision

K923398 · Product code: **DTE** · Cardiovascular
Source: https://www.510kdatabase.net/k923398/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pulse-generator, Pacemaker, External (DTE)
Date received	Jul 10, 1992
Decision date	Aug 14, 1992
Days to decision	35 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Seamed Corp.**
Location	Walker, MI, US
Contact	MARCIA A PAGE
510(k) history	18 submissions · 18 cleared · 1982-1992

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k923398/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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