FDA 510(k) Premarket Notification

K823371 DURAPULSE

CLEARED

Dec 22, 1982
40 days to decision

K823371 · Product code: **DXY** · Cardiovascular
Source: https://www.510kdatabase.net/k823371/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implantable Pacemaker Pulse-generator (DXY)
Date received	Nov 12, 1982
Decision date	Dec 22, 1982
Days to decision	40 days
Third-party review	No

APPLICANT

Company	**Cpm International, Inc.**
Location	Walker, MI, US
510(k) history	1 submissions · 1 cleared · 1982-1982