FDA 510(k) Premarket Notification

K781835 PULSTRON MODEL 100

CLEARED

Dec 21, 1978
52 days to decision

K781835 · Product code: **DXY** · Cardiovascular
Source: https://www.510kdatabase.net/k781835/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implantable Pacemaker Pulse-generator (DXY)
Date received	Oct 30, 1978
Decision date	Dec 21, 1978
Days to decision	52 days
Third-party review	No

APPLICANT

Company	**Micro-Rel**
Location	Mchenry, IL, US
510(k) history	1 submissions · 1 cleared · 1978-1978