FDA 510(k) Premarket Notification

K791920 CARDIAC PACEMAKER P4000 SER. & P1000

CLEARED

Nov 29, 1979
65 days to decision

K791920 · Product code: **DXY** · Cardiovascular
Source: https://www.510kdatabase.net/k791920/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implantable Pacemaker Pulse-generator (DXY)
Date received	Sep 25, 1979
Decision date	Nov 29, 1979
Days to decision	65 days
Third-party review	No

APPLICANT

Company	**Vitatron Medical BV**
Location	Mchenry, IL, US
510(k) history	19 submissions · 19 cleared · 1976-1986