FDA 510(k) Premarket Notification

K800285 MODEL 5985 PACEMAKER PULSE GENERATOR

CLEARED

May 20, 1980
102 days to decision

K800285 · Product code: **DXY** · Cardiovascular
Source: https://www.510kdatabase.net/k800285/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implantable Pacemaker Pulse-generator (DXY)
Date received	Feb 8, 1980
Decision date	May 20, 1980
Days to decision	102 days
Third-party review	No

APPLICANT

Company	**Medtronic Vascular**
Location	Walker, MI, US
510(k) history	475 submissions · 453 cleared · 1977-2023