FDA 510(k) Premarket Notification

K781252 GENERATOR, PULSE, MODEL 5997

CLEARED

Oct 3, 1978
74 days to decision

K781252 · Product code: **DXY** · Cardiovascular
Source: https://www.510kdatabase.net/k781252/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implantable Pacemaker Pulse-generator (DXY)
Date received	Jul 21, 1978
Decision date	Oct 3, 1978
Days to decision	74 days
Third-party review	No

APPLICANT

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