FDA 510(k) Premarket Notification

K781208 GENERATORS, PULSE, MODELS 5988/5989

CLEARED

Oct 3, 1978
81 days to decision

K781208 · Product code: **DXY** · Cardiovascular
Source: https://www.510kdatabase.net/k781208/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implantable Pacemaker Pulse-generator (DXY)
Date received	Jul 14, 1978
Decision date	Oct 3, 1978
Days to decision	81 days
Third-party review	No

APPLICANT

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