FDA 510(k) Premarket Notification

K780809 GENERATOR, PULSE MODELS 5920/5921

CLEARED

Jul 28, 1978
71 days to decision

K780809 · Product code: **DXY** · Cardiovascular
Source: https://www.510kdatabase.net/k780809/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implantable Pacemaker Pulse-generator (DXY)
Date received	May 18, 1978
Decision date	Jul 28, 1978
Days to decision	71 days
Third-party review	No

APPLICANT

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