FDA 510(k) Premarket Notification

K780421 GENERATOR, PULSE, CARDIAC, IMPLANTABLE

CLEARED

Jul 7, 1978
114 days to decision

K780421 · Product code: **DXY** · Cardiovascular
Source: https://www.510kdatabase.net/k780421/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implantable Pacemaker Pulse-generator (DXY)
Date received	Mar 15, 1978
Decision date	Jul 7, 1978
Days to decision	114 days
Third-party review	No

APPLICANT

Company	**Telectronics, Inc.**
Location	Mchenry, IL, US
510(k) history	107 submissions · 107 cleared · 1977-1990