FDA 510(k) Premarket Notification

K800387 PULSE GENERATORS MODELS 657 & 677

CLEARED

May 2, 1980
70 days to decision

K800387 · Product code: **DXY** · Cardiovascular
Source: https://www.510kdatabase.net/k800387/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implantable Pacemaker Pulse-generator (DXY)
Date received	Feb 22, 1980
Decision date	May 2, 1980
Days to decision	70 days
Third-party review	No

APPLICANT

Company	**Siemens Elema AB**
Location	Mchenry, IL, US
510(k) history	63 submissions · 60 cleared · 1978-2003