FDA 510(k) Premarket Notification

K790670 PULSE GENERATOR MODEL 629

CLEARED

Jun 27, 1979
82 days to decision

K790670 · Product code: **DXY** · Cardiovascular
Source: https://www.510kdatabase.net/k790670/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implantable Pacemaker Pulse-generator (DXY)
Date received	Apr 6, 1979
Decision date	Jun 27, 1979
Days to decision	82 days
Third-party review	No

APPLICANT

Company	**Elema-Schonander, Inc.**
Location	Mchenry, IL, US
510(k) history	11 submissions · 11 cleared · 1977-1993