FDA 510(k) Premarket Notification

K770135 LEAD MODIFICATION

CLEARED

Feb 7, 1977
14 days to decision

K770135 · Product code: **DXY** · Cardiovascular
Source: https://www.510kdatabase.net/k770135/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implantable Pacemaker Pulse-generator (DXY)
Date received	Jan 24, 1977
Decision date	Feb 7, 1977
Days to decision	14 days
Third-party review	No

APPLICANT

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