FDA 510(k) Premarket Notification

K833519 PULSE GENERATOR MODEL 688

CLEARED

Jan 30, 1984
111 days to decision

K833519 · Product code: **DXY** · Cardiovascular
Source: https://www.510kdatabase.net/k833519/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implantable Pacemaker Pulse-generator (DXY)
Date received	Oct 11, 1983
Decision date	Jan 30, 1984
Days to decision	111 days
Third-party review	No

APPLICANT

Company	**Burditt & Calkins-Siemens-Elema**
Location	Mchenry, IL, US
510(k) history	10 submissions · 10 cleared · 1976-1984