FDA 510(k) Premarket Notification

K791219 UNILITH PULSE GENERATOR

CLEARED

Jul 30, 1979
27 days to decision

K791219 · Product code: **DXY** · Cardiovascular
Source: https://www.510kdatabase.net/k791219/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implantable Pacemaker Pulse-generator (DXY)
Date received	Jul 3, 1979
Decision date	Jul 30, 1979
Days to decision	27 days
Third-party review	No

APPLICANT

Company	**Ela Medical, Inc.**
Location	Mchenry, IL, US
510(k) history	43 submissions · 36 cleared · 1979-2004

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k791219/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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