FDA 510(k) Premarket Notification

K841636 NEOS M

CLEARED

Jun 25, 1984
67 days to decision

K841636 · Product code: **DXY** · Cardiovascular
Source: https://www.510kdatabase.net/k841636/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implantable Pacemaker Pulse-generator (DXY)
Date received	Apr 19, 1984
Decision date	Jun 25, 1984
Days to decision	67 days
Third-party review	No

APPLICANT

Company	**Biotronik Sales, Inc.**
Location	Mchenry, IL, US
510(k) history	41 submissions · 41 cleared · 1980-1988

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k841636/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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