

K830862 NEDS-01 & EPR-500May 25, 1983
68 days to decisionK830862 · Product code: **DXY** · CardiovascularSource: <https://www.510kdatabase.net/k830862/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implantable Pacemaker Pulse-generator (DXY)
Date received	Mar 18, 1983
Decision date	May 25, 1983
Days to decision	68 days
Third-party review	No

APPLICANT

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

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Device record: <https://www.510kdatabase.net/k830862/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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