

K853058 NEOS - M ABPSep 13, 1985
56 days to decisionK853058 · Product code: **DXY** · Cardiovascular
Source: <https://www.510kdatabase.net/k853058/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implantable Pacemaker Pulse-generator (DXY)
Date received	Jul 19, 1985
Decision date	Sep 13, 1985
Days to decision	56 days
Third-party review	No

APPLICANT

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

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