

K844794 LEPTOS PULSE GENERATORApr 18, 1985
129 days to decisionK844794 · Product code: **DXY** · CardiovascularSource: <https://www.510kdatabase.net/k844794/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implantable Pacemaker Pulse-generator (DXY)
Date received	Dec 10, 1984
Decision date	Apr 18, 1985
Days to decision	129 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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