

K894494 LABELING CHANGES TO PULSE GENE. & PULSE GENE. LEADOct 17, 1989
90 days to decisionK894494 · Product code: **DXY** · Cardiovascular
Source: <https://www.510kdatabase.net/k894494/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implantable Pacemaker Pulse-generator (DXY)
Date received	Jul 19, 1989
Decision date	Oct 17, 1989
Days to decision	90 days
Third-party review	No

APPLICANT

Company	Biotronik, GmbH & Co.
Location	Lake Oswego, OR, US
Contact	STOUT, MD
510(k) history	18 submissions · 17 cleared · 1989-2000

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