

K905087 TRIOS 02May 7, 1991
175 days to decisionK905087 · Product code: **DXY** · Cardiovascular
Source: <https://www.510kdatabase.net/k905087/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implantable Pacemaker Pulse-generator (DXY)
Date received	Nov 13, 1990
Decision date	May 7, 1991
Days to decision	175 days
Third-party review	No

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k905087/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated July 4, 2026