

K863878 TRIOS-M VS-1 PULSE GENERATORDec 10, 1986
65 days to decisionK863878 · Product code: **DXY** · CardiovascularSource: <https://www.510kdatabase.net/k863878/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implantable Pacemaker Pulse-generator (DXY)
Date received	Oct 6, 1986
Decision date	Dec 10, 1986
Days to decision	65 days
Third-party review	No

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k863878/>; 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 7, 2026