

K896184 KALOS 05 PULSE GENERATORJan 18, 1990
85 days to decisionK896184 · Product code: **DXY** · Cardiovascular
Source: <https://www.510kdatabase.net/k896184/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implantable Pacemaker Pulse-generator (DXY)
Date received	Oct 25, 1989
Decision date	Jan 18, 1990
Days to decision	85 days
Third-party review	No

APPLICANT

Company	Biotronik Cardiac Pacemakers
Location	Lake Oswego, CA, US
Contact	STOUT, MD
510(k) history	3 submissions · 3 cleared · 1989-1990

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