

**K923026 PIKOS 01-A AND PIKOS E01-A IMPLANTABLE
PACEMAKER**Aug 19, 1993
422 days to decisionK923026 · Product code: **DXY** · Cardiovascular
Source: <https://www.510kdatabase.net/k923026/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implantable Pacemaker Pulse-generator (DXY)
Date received	Jun 23, 1992
Decision date	Aug 19, 1993
Days to decision	422 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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