

K901332 PK-55 ANDOVER MEDICAL PART #5455 LABEL CHANGEMay 9, 1990
48 days to decisionK901332 · Product code: **DTC** · Cardiovascular
Source: <https://www.510kdatabase.net/k901332/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Analyzer, Pacemaker Generator Function (DTC)
Date received	Mar 22, 1990
Decision date	May 9, 1990
Days to decision	48 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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