

**K903927 LABEL CHANGE UNIPOLAR ENDOCARDIAL LEAD,  
DJP 45-UP**Oct 16, 1990  
57 days to decisionK903927 · Product code: **DTB** · Cardiovascular  
Source: <https://www.510kdatabase.net/k903927/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Permanent Pacemaker Electrode (DTB)
Date received	Aug 20, 1990
Decision date	Oct 16, 1990
Days to decision	57 days
Third-party review	No

**APPLICANT**

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Company	<b>Biotronik, GmbH &amp; Co.</b>
Location	Lake Oswego, OR, US
Contact	STOUT, MD
510(k) history	18 submissions · 17 cleared · 1989-2000

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k903927/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated July 4, 2026