

**K903928 LABEL CHANGE UNIPOLAR ENDOCARDIAL LEAD
DJP 53-UP**Oct 16, 1990
57 days to decisionK903928 · Product code: **DTB** · Cardiovascular
Source: <https://www.510kdatabase.net/k903928/>**SUBMISSION DETAILS**

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

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k903928/>; 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 4, 2026