

**K896824 BIOTRONIK'S PS-ENDOCARDIAL LEADS**Aug 8, 1990  
247 days to decisionK896824 · Product code: **DTB** · CardiovascularSource: <https://www.510kdatabase.net/k896824/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Permanent Pacemaker Electrode (DTB)
Date received	Dec 4, 1989
Decision date	Aug 8, 1990
Days to decision	247 days
Third-party review	No

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k896824/>; 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