

**K953044 UNIPOLAR & BIOPOLAR IMPLANTABLE  
ENDOCARDIAL PACING LEADS, WITH SILICONE RUBBER  
INSULATION & PASSIVE FIXATION**Sep 27, 1996  
455 days to decisionK953044 · Product code: **DTB** · Cardiovascular  
Source: <https://www.510kdatabase.net/k953044/>**SUBMISSION DETAILS**

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Decision	PT
Submission type	Traditional
Device classification	Permanent Pacemaker Electrode (DTB)
Date received	Jun 30, 1995
Decision date	Sep 27, 1996
Days to decision	455 days
Third-party review	No

**APPLICANT**

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Company	<b>Biotronik, Inc.</b>
Location	Lake Oswego, OR, US
Contact	JOSEPH J SCHOWEBEL
Website	<a href="https://www.biotronik.com">https://www.biotronik.com</a>
510(k) history	85 submissions · 67 cleared · 1994-2026

Biotronik, Inc. designs and manufactures advanced active implants for cardiac rhythm management, monitoring, and electrophysiology. The company operates with a manufacturing facility in Lake Oswego, Oregon, and serves patients globally through innovative cardiovascular solutions. Biotronik has received FDA 510(k) clearances from total submissions since its first clearance in 1994. The company specializes exclusively in cardiovascular devices, including pacing systems, implantable cardioverter defibrillators, cardiac resynchronization therapies, and electrophysiology catheters.