

**K964604 BIPOLAR IMPLANTABLE ENDOCARDIAL PACING  
LEADS, WITH SILICONE RUBBER INSULATION AND PASSIVE  
FIXATION**Mar 10, 1997  
112 days to decisionK964604 · Product code: **DTB** · Cardiovascular  
Source: <https://www.510kdatabase.net/k964604/>**SUBMISSION DETAILS**

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Decision	PT
Submission type	Traditional
Device classification	Permanent Pacemaker Electrode (DTB)
Date received	Nov 18, 1996
Decision date	Mar 10, 1997
Days to decision	112 days
Third-party review	No

**APPLICANT**

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Company	<b>Biotronik, Inc.</b>
Location	Lake Oswego, OR, US
Contact	JOSEPH J SCHWOEBEL, RAC
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 cathe...