

**K971930 BK-N SEALING CAP**Aug 14, 1997  
79 days to decisionK971930 · Product code: **DTD** · Cardiovascular  
Source: <https://www.510kdatabase.net/k971930/>**SUBMISSION DETAILS**

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Decision	PT
Submission type	Traditional
Device classification	Pacemaker Lead Adaptor (DTD)
Date received	May 27, 1997
Decision date	Aug 14, 1997
Days to decision	79 days
Third-party review	No

**APPLICANT**

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Company	<b>Biotronik, Inc.</b>
Location	Lake Oswego, OR, US
Contact	KENNETH JENSEN
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...

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