FDA 510(k) Premarket Notification

K970204 BK-A

CLEARED

Apr 29, 1997
98 days to decision

K970204 · Product code: **DTD** · Cardiovascular
Source: https://www.510kdatabase.net/k970204/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pacemaker Lead Adaptor (DTD)
Date received	Jan 21, 1997
Decision date	Apr 29, 1997
Days to decision	98 days
Third-party review	No
Summary / Statement	Summary
Other names	BK-B; BK-IS SEALING CAP

APPLICANT

Company	**Biotronik, Inc.**
Location	Lake Oswego, OR, US
Contact	Joseph J Schwoebel
Website	https://www.biotronik.com
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...