

K003454 A1-CS-SB Y-ADAPTER, MODEL 124 871Jan 18, 2001
72 days to decisionK003454 · Product code: **DTD** · Cardiovascular
Source: <https://www.510kdatabase.net/k003454/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent - ST
Submission type	Special
Device classification	Pacemaker Lead Adaptor (DTD)
Date received	Nov 7, 2000
Decision date	Jan 18, 2001
Days to decision	72 days
Third-party review	No

APPLICANT

Company	Biotronik, Inc.
Location	Lake Oswego, OR, US
Contact	JON BURMBAUGH
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...

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