FDA 510(k) Premarket Notification

K061212 BIOTRONIK ENDOCARDIAL PACING LEADS

CLEARED

Jul 10, 2006
70 days to decision

K061212 · Product code: **DTB** · Cardiovascular
Source: https://www.510kdatabase.net/k061212/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Permanent Pacemaker Electrode (DTB)
Date received	May 1, 2006
Decision date	Jul 10, 2006
Days to decision	70 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Biotronik, Inc.**
Location	Lake Oswego, OR, US
Contact	Jon Brumbaugh
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...