

K001413 ELOX 45-BP, MODEL 330 132, EFH-27, MODEL 331 549, EXTENSION TOOL, MODEL 331 668Jun 2, 2000
29 days to decisionK001413 · Product code: **DTB** · Cardiovascular
Source: <https://www.510kdatabase.net/k001413/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent - ST
Submission type	Special
Device classification	Permanent Pacemaker Electrode (DTB)
Date received	May 4, 2000
Decision date	Jun 2, 2000
Days to decision	29 days
Third-party review	No

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...

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