

**K023205 ELOX P 45-BP**Apr 24, 2003  
211 days to decisionK023205 · Product code: **DTB** · Cardiovascular  
Source: <https://www.510kdatabase.net/k023205/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent - ST
Submission type	Traditional
Device classification	Permanent Pacemaker Electrode (DTB)
Date received	Sep 25, 2002
Decision date	Apr 24, 2003
Days to decision	211 days
Third-party review	No
Other names	ELOX P 53-BP; ELOX P 60-BP

**APPLICANT**

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Company	<b>Biotronik, Inc.</b>
Location	Lake Oswego, OR, US
Contact	Jon Brumbaugh
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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