

**K965106 ELC 35-UP MODEL NUMBER 116015 AND ELC 54-UP  
MODEL NUMBER 115606**Jan 27, 1998  
403 days to decisionK965106 · Product code: **DTB** · Cardiovascular  
Source: <https://www.510kdatabase.net/k965106/>**SUBMISSION DETAILS**

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Decision	PT
Submission type	Traditional
Device classification	Permanent Pacemaker Electrode (DTB)
Date received	Dec 20, 1996
Decision date	Jan 27, 1998
Days to decision	403 days
Third-party review	No

**APPLICANT**

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Company	<b>Biotronik, Inc.</b>
Location	Lake Oswego, OR, US
Contact	Joseph J Schwoebel
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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