

**K010281 MEROX BIPOLAR HIGH IMPEDANCE LEAD MODELS:
MEX 53/13-BP**Apr 9, 2002
434 days to decisionK010281 · Product code: **DTB** · Cardiovascular
Source: <https://www.510kdatabase.net/k010281/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Permanent Pacemaker Electrode (DTB)
Date received	Jan 30, 2001
Decision date	Apr 9, 2002
Days to decision	434 days
Third-party review	No
Summary / Statement	Summary
Other names	60/15-BP; 45-JBP; 53-JBP

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 catheters.