

**K001736 GALEO HYDRO AND GALEO HYDRO J-TIP**Aug 2, 2000  
56 days to decisionK001736 · Product code: **DQX** · Cardiovascular  
Source: <https://www.510kdatabase.net/k001736/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Wire, Guide, Catheter (DQX)
Date received	Jun 7, 2000
Decision date	Aug 2, 2000
Days to decision	56 days
Third-party review	No
Summary / Statement	Summary

**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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