FDA 510(k) Premarket Notification

CLEARED

K982272 GALEO HS 014 MODEL 117 130, GALEO S 014 MODEL 115 488, GALEAO M 014 MODEL 114156, GALEO F 014 MODEL 115 487 GALEO HF 018

Jan 8, 1999
193 days to decision

K982272 · Product code: **DQX** · Cardiovascular
Source: https://www.510kdatabase.net/k982272/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wire, Guide, Catheter (DQX)
Date received	Jun 29, 1998
Decision date	Jan 8, 1999
Days to decision	193 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Biotronik, Inc.**
Location	Lake Oswego, OR, US
Contact	DAVID MAKANANI
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...