

K082933 PASSEO-35 PTA CATHETERNov 3, 2008
33 days to decisionK082933 · Product code: **DQY** · Cardiovascular
Source: <https://www.510kdatabase.net/k082933/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Percutaneous (DQY)
Date received	Oct 1, 2008
Decision date	Nov 3, 2008
Days to decision	33 days
Third-party review	No
Summary / Statement	Summary

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 cathe...
