FDA 510(k) Premarket Notification

K250706 Passeo-35 Xeo Peripheral Dilatation Catheter

CLEARED

Apr 4, 2025
25 days to decision

K250706 · Product code: **LIT** · Cardiovascular
Source: https://www.510kdatabase.net/k250706/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Angioplasty, Peripheral, Transluminal (LIT)
Date received	Mar 10, 2025
Decision date	Apr 4, 2025
Days to decision	25 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Passeo-18 Peripheral Dilatation Catheters; Passeo-14 Peripheral Dilatation Catheter; Oscar Peripheral Multifunctional Catheter System; Pantera Pro Percutaneous Transluminal Coronary Angioplasty Catheter; Pantera LEO Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheter

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...