

K060655 SCOUTPRO 8F, MODELS 342 262Apr 4, 2006
22 days to decisionK060655 · Product code: **DQY** · Cardiovascular
Source: <https://www.510kdatabase.net/k060655/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Percutaneous (DQY)
Date received	Mar 13, 2006
Decision date	Apr 4, 2006
Days to decision	22 days
Third-party review	No
Summary / Statement	Summary
Other names	HEMOSTATIC VALVE, MODELS 345 968; HOOK GUIDING CATHETER, MODELS 342 263; MULTI-PURPOSE H

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...
