

K131978 SELECTRA ACCESSORY KIT, SELECTRA SLITTER TOOLAug 23, 2013
56 days to decisionK131978 · Product code: **DQY** · Cardiovascular
Source: <https://www.510kdatabase.net/k131978/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Percutaneous (DQY)
Date received	Jun 28, 2013
Decision date	Aug 23, 2013
Days to decision	56 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 catheters.

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k131978/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 8, 2026