

**K240787 Selectra 3D Lead Delivery System (443624-443629, 451789-451791)**Sep 12, 2024  
174 days to decisionK240787 · Product code: **DQY** · Cardiovascular  
Source: <https://www.510kdatabase.net/k240787/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous (DQY)
Date received	Mar 22, 2024
Decision date	Sep 12, 2024
Days to decision	174 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Selectra Slitter Tool (383119); Selectra Accessory Kit (375518)

**APPLICANT**

Company	<b>Biotronik, Inc.</b>
Location	Lake Oswego, OR, US
Contact	Jon Brumbaugh
Website	<a href="https://www.biotronik.com">https://www.biotronik.com</a>
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.

**CLINICAL EVIDENCE - NCT04323670****Master Study Investigating the Guiding Catheter Selectra 3D**

Status	Completed - <i>No results published to ClinicalTrials.gov</i>
Enrollment	157 patients (actual)
Study sites	1 site
Condition studied	Pacemaker DDD
Primary purpose	Other
Study type	Interventional
Study design	Single group
Masking	Open label
Completion date	Dec 22, 2022
Sponsor	Biotronik SE & Co. KG (Industry)

**Primary outcome**

Selectra 3D-related SADE-free rate

**Secondary outcome**

Successful implantation rate

Source: ClinicalTrials.gov / U.S. National Library of Medicine - [clinicaltrials.gov/study/NCT04323670](https://clinicaltrials.gov/study/NCT04323670)

