

K222037 Selectra Lead Implantation SystemJul 19, 2022
8 days to decisionK222037 · Product code: **DQY** · Cardiovascular
Source: <https://www.510kdatabase.net/k222037/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Catheter, Percutaneous (DQY) |
| Date received | Jul 11, 2022 |
| Decision date | Jul 19, 2022 |
| Days to decision | 8 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | 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.