FDA 510(k) Premarket Notification

# K021217 AROX 53-BP

**CLEARED**

May 1, 2002
14 days to decision

K021217 · Product code: **DTB** · Cardiovascular
Source: https://www.510kdatabase.net/k021217/

**SUBMISSION DETAILS**

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Permanent Pacemaker Electrode (DTB) |
| Date received | Apr 17, 2002 |
| Decision date | May 1, 2002 |
| Days to decision | 14 days |
| Third-party review | No |
| Summary / Statement | Summary |
| Other names | AROX 60-BP; AROX 45-JBP; AROX 53-JBP |

**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...