FDA 510(k) Premarket Notification

**NOT CLEARED**

# K970388 A1-A,ABP,B,MBP, LEAD CONNECTORS

Aug 14, 1997
192 days to decision

K970388 · Product code: **DTD** · Cardiovascular
Source: https://www.510kdatabase.net/k970388/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | PT |
| Submission type | Traditional |
| Device classification | Pacemaker Lead Adaptor (DTD) |
| Date received | Feb 3, 1997 |
| Decision date | Aug 14, 1997 |
| Days to decision | 192 days |
| Third-party review | No |
| Other names | PEH ADAPTER SLEEVE |

## APPLICANT

| | |
|---|---|
| Company | **Biotronik, Inc.** |
| Location | Lake Oswego, OR, US |
| Contact | Joseph J Schwoebel |
| 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...