

**K171514 BioMonitor 2-AF, BioMonitor 2-S, FIT - Fast Insert Tool  
1 + 2, Set**Jun 29, 2017  
36 days to decisionK171514 · Product code: **MXD** · Cardiovascular  
Source: <https://www.510kdatabase.net/k171514/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Recorder, Event, Implantable Cardiac, (with Arrhythmia Detection) (MXD)
Date received	May 24, 2017
Decision date	Jun 29, 2017
Days to decision	36 days
Third-party review	No
Summary / Statement	Summary

**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.

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k171514/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 1, 2026