FDA 510(k) Premarket Notification

CLEARED

K170628 BioMonitor 2-AF, BioMonitor 2-S

Mar 31, 2017
29 days to decision

K170628 · Product code: **MXD** · Cardiovascular
Source: https://www.510kdatabase.net/k170628/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Recorder, Event, Implantable Cardiac, (with Arrhythmia Detection) (MXD)
Date received	Mar 2, 2017
Decision date	Mar 31, 2017
Days to decision	29 days
Third-party review	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 cathe...