

K822689 PORTABLE MONITORING & SCREENING SPIROM.Jul 12, 1983
312 days to decisionK822689 · Product code: **BZK** · Anesthesiology
Source: <https://www.510kdatabase.net/k822689/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Spirometer, Monitoring (w/wo Alarm) (BZK)
Date received	Sep 3, 1982
Decision date	Jul 12, 1983
Days to decision	312 days
Third-party review	No

APPLICANT

Company	Boehringer Laboratories
Location	Mchenry, IL, US
Website	http://www.boehringerlabs.com
510(k) history	38 submissions · 38 cleared · 1976-2024

Boehringer Laboratories is a family-owned American medical technology company headquartered in Phoenixville, Pennsylvania, with operations in McHenry, US. The company specializes in respiratory therapy and minimally invasive surgical devices. Boehringer Laboratories has maintained a strong FDA 510(k) regulatory record since 1976. The company has received FDA 510(k) clearances from total submissions, with no denied submissions. Recent clearances span 2024, demonstrating continued active development. The company's portfolio focuses primarily on anesthesiology devices, inclu...