

K760971 POSITIVE DISPLACEMENT SPIROMETERDec 9, 1976
35 days to decisionK760971 · Product code: **BZK** · Anesthesiology
Source: <https://www.510kdatabase.net/k760971/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Spirometer, Monitoring (w/wo Alarm) (BZK) |
| Date received | Nov 4, 1976 |
| Decision date | Dec 9, 1976 |
| Days to decision | 35 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...

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Device record: <https://www.510kdatabase.net/k760971/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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