

K810437 BREATH METERMay 1, 1981
71 days to decisionK810437 · Product code: **BZG** · Anesthesiology
Source: <https://www.510kdatabase.net/k810437/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Spirometer, Diagnostic (BZG)
Date received	Feb 19, 1981
Decision date	May 1, 1981
Days to decision	71 days
Third-party review	No

APPLICANT

Company	Fred Sammons, Inc.
Location	Mchenry, IL, US
Website	https://www.sammons-preston.com
510(k) history	278 submissions · 278 cleared · 1976-1988

Fred Sammons, Inc. is a medical device company based in McHenry, US, specializing in rehabilitation products and assistive devices for patient care and therapy. The company has received FDA 510(k) clearances from total submissions, with 88% focused on Physical Medicine devices. FDA 510(k) clearances span from 1976 to 1988, establishing a historical regulatory record in therapeutic aids, orthotic supports, and mobility assistance equipment. Notable cleared devices include orthotic plastics, arm slings, splints, traction exercise equipment, and specialized assessment tools....
