FDA 510(k) Premarket Notification

K761116 BREATH CONTROL GAME

CLEARED

Dec 2, 1976
13 days to decision

K761116 · Product code: **ILT** · Physical Medicine
Source: https://www.510kdatabase.net/k761116/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Adaptor, Recreational (ILT)
Date received	Nov 19, 1976
Decision date	Dec 2, 1976
Days to decision	13 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....

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k761116/ Data sourced from FDA 510(k) public records (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. - Generated May 28, 2026