

K801710 BK-5315-01 FOAM HAND EXERCISER, SMALLAug 7, 1980
14 days to decisionK801710 · Product code: **ION** · Physical MedicineSource: <https://www.510kdatabase.net/k801710/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Exerciser, Non-measuring (ION)
Date received	Jul 24, 1980
Decision date	Aug 7, 1980
Days to decision	14 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.netDevice record: <https://www.510kdatabase.net/k801710/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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