

K823649 THERMOELASTOMER HOT/COLD COMPRESS BK7186Jan 21, 1983
46 days to decisionK823649 · Product code: **IME** · Physical MedicineSource: <https://www.510kdatabase.net/k823649/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pack, Hot Or Cold, Reusable (IME)
Date received	Dec 6, 1982
Decision date	Jan 21, 1983
Days to decision	46 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....

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