

**K823622 INSULATED THERMOELASTOMER MITT**Dec 30, 1982  
24 days to decisionK823622 · Product code: **IMA** · Physical MedicineSource: <https://www.510kdatabase.net/k823622/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pack, Heat, Moist (IMA)
Date received	Dec 6, 1982
Decision date	Dec 30, 1982
Days to decision	24 days
Third-party review	No

**APPLICANT**

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Company	<b>Fred Sammons, Inc.</b>
Location	Mchenry, IL, US
Website	<a href="https://www.sammons-preston.com">https://www.sammons-preston.com</a>
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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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k823622/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 28, 2026