FDA 510(k) Premarket Notification

K821640 ORTHOTIC FABRICATION ACCESSORIES

CLEARED

Jun 11, 1982
8 days to decision

K821640 · Product code: **IQI** · Physical Medicine
Source: https://www.510kdatabase.net/k821640/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthosis, Limb Brace (IQI)
Date received	Jun 3, 1982
Decision date	Jun 11, 1982
Days to decision	8 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....