FDA 510(k) Premarket Notification

CLEARED

K760301 GONIOMETER, MED. INTER. STAND. BK-7512

Sep 8, 1976
47 days to decision

K760301 · Product code: **KQW** · Neurology
Source: https://www.510kdatabase.net/k760301/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Goniometer, Nonpowered (KQW)
Date received	Jul 23, 1976
Decision date	Sep 8, 1976
Days to decision	47 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....