FDA 510(k) Premarket Notification

**CLEARED**

# K801716 BK-7505 RADIOPAQUE GONIOMETER, 8

Aug 4, 1980
11 days to decision

K801716 · Product code: **KQW** · Neurology
Source: https://www.510kdatabase.net/k801716/

**SUBMISSION DETAILS**

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Goniometer, Nonpowered (KQW) |
| Date received | Jul 24, 1980 |
| Decision date | Aug 4, 1980 |
| Days to decision | 11 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....