

K970275 PATIENT RESTRAINTSApr 11, 1997
78 days to decisionK970275 · Product code: **FMQ** · General Hospital
Source: <https://www.510kdatabase.net/k970275/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Restraint, Protective (FMQ)
Date received	Jan 23, 1997
Decision date	Apr 11, 1997
Days to decision	78 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Fla Orthopedics, Inc.
Location	Miami Lakes, FL, US
Contact	RHONDA FALK
510(k) history	4 submissions · 4 cleared · 1997-1997

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k970275/> Data sourced from FDA 510(k) public records (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. - Generated July 6, 2026