FDA 510(k) Premarket Notification

K970275 PATIENT RESTRAINTS

CLEARED

Apr 11, 1997
78 days to decision

K970275 · 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