

K963485 SILICONE RUBBER CUFF/DISPOSABLE FLEECE LINER'S WEB TORSO RESRAINT,NYON LIMB HOLDER,VINYL LIMB HOLDER,NYLON BED RESTRAINS

Nov 22, 1996
80 days to decision

K963485 · Product code: **FMQ** · General Hospital
Source: <https://www.510kdatabase.net/k963485/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Restraint, Protective (FMQ)
Date received	Sep 3, 1996
Decision date	Nov 22, 1996
Days to decision	80 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Humane Restraint, Inc.
Location	Waunakee, WI, US
Contact	STACY R SCHULTZ
510(k) history	1 submissions · 1 cleared · 1996-1996

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Device record: <https://www.510kdatabase.net/k963485/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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