



AliMed® inc.

297 High Street
Dedham, MA 02026

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K 963528

510(k) SUMMARY

Various Procedural Restraints

Applicant: AliMed®, inc.
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Trade Names: AliMed® Positioning & Safety Straps, Semi-Disposable Arm Straps,
Stretcher Straps
Common Name: Strap or Restraint
Classification Name: Patient Restraint

Legally Marketed Devices to Which Substantial Equivalence is claimed:

Various Preamendments straps and restraints.

510(k) SUMMARY-continued

Description of Device: The devices are fabricated various lengths and widths as described in advertising. The closure is "hook and loop".

Intended Use of the Device: Reduction of patient movement, or restrain of patient, during medical procedure, during transportation of the patient, or in other situations deemed appropriate by the health care facility.

CODE	NAME	SIZE	FIRST MANUFACTURED	USE
9-931	Universal Body Strap	5" x 65"	1990	Positioning & safety strap
9-930	Wrist/Ankle Straps	1 @ 5" x 45" 2 @ 2" x 12"	1991*	Positioning patient on table
9-950	Wrist Straps	2 @ 2" x 12"	1991	Restraint wrists/arms
95-022	Semi-Disposable Arm Straps	2" x 18"	1986	Bulk arm strap
7686	Wheel Stretcher Strap	2" x 62"	1978**	Stretcher strap
7687	Wheel Stretcher Strap	2" x 66"	1978**	Stretcher strap
7688	Wheel Stretcher Strap	2" x 72"	1978**	Stretcher strap

* = Converted from Distributed by to Manufactured by in the year shown. First year of sale by original company not known at this time.

** = Converted from Distributed by to Manufactured for, by the actual manufacturer. Date shown is that firm's drawing date.

Comparative Information: Pre-1976 catalogs were not found which showed devices such as those contained in this notification. However, it is understood that these types of devices were in use prior to the Medical Device Amendment and others were introduced after the Act.

Biocompatibility: Based on the materials, and the method of use (topological), it is unlikely that any concern of this nature would develop.

User Experience: The firm has received no information related to a death, serious injury or allergic reaction to the materials used during the time these devices have been marketed.