



AliMed® inc.

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297 High Street
Dedham, MA 02026

OCT 28 1996

510(k) SUMMARY

Strap Wedge

Applicant:

**AliMed®, inc.
297 High Street
Dedham, MA 02026**

Contact: Jonathan C. Bretz

**Telephone: 617-329-2900
FAX: 617-329-8392**

Submitted by:

**Curtin & Associates International
1200 East Street
Dedham, MA 02026**

Contact: Donald A. Lincoln

**Telephone: 617-329-1955
FAX: 617-329-2529**

Date this Summary was prepared: 30 August 1996

Trade Name: Strap Wedge

Common Name: Strap Wedge

Classification Name: Patient Restraint

Legally Marketed Devices to Which Substantial Equivalence is claimed:

Various Preamendments strap and support assemblies.

510(k) SUMMARY-continued

Description of Device: The Strap Wedge is an assembly of covered foam blocks to which five (5) restraining straps have been sewn.

Intended Use of the Device: Position and secure a patient in the prone or supine positions.

User Experience: There have been no reports of death or serious injury received by the firm during the time these devices have been manufactured. Device was first manufactured in September of 1995.

Biocompatibility: Based on the topological use of this device and the materials used, it is unlikely that biocompatibility difficulties would arise. In addition, the firm has received no information from users indicating that a biocompatibility question has developed.

Comparative Information: The firm has been unable to obtain pre-1976 information related to specific devices of this type. However, the use of covered foam padding and straps such as are incorporated in this device appear to have been in use before the Medical Device Amendment as well as after the date of the amendment.