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**510(k) Summary of Safety and Effectiveness**

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**Preparation Date:** August 30, 1996

**Device Name(s):** Limb Holders (protective restraints)

**Proprietary Names:** Foam Limb Holder w/Quick Release Buckle  
Polyester Pile Wrist/Ankle Restraint  
Soft Flannel Wrist/Ankle Restraint  
Wrist Restraint, Universal

**Classification Name:** Protective Restraint

**Comparison Device:** Same as above.

**Intended Use:** "The Zimmer line of restraints is intended for restless, confused, elderly, or unsteady patients. They help prevent such patients from injuring themselves or clinical personnel.

The most common emergency indications for patient restraints are: emotional/psychological disturbance, threatened or attempted suicide, suspected drug/alcohol abuse, and seizure or cardiac arrest. Restraints may also be indicated for post-op patients in recovery, patients under sedation, and patients suffering from stroke, neuromuscular disorders, or Alzheimer's disease.

Zimmer restraints are not intended for patients who may be exceptionally violent. Such patients may require devices made from heavier materials and specifically designed for patients with serious mental disturbances."

**Comparative Data:** The devices used for comparative purposes are the limb holders as described in this submission. (See Tab G - June 14, 1996 Meeting Minutes, HIMA Body Holder Task Force and FDA CDRH - for rationale.)

These limb holders are currently exempt from 510(k) Premarket Notification Procedures and Good Manufacturing Practice Regulations, and they are legally marketed by Zimmer Patient Care Division as of the date of this submission, August 30, 1996. These limb holders have been manufactured and in commercial distribution for over 20 years.

The use of all patient restraints in nursing homes is subject to Health Care Financing Administration Regulations which prohibit the use of any restraint, physical or chemical, imposed for the purpose of discipline or convenience.



Further, the "Revised Standards for Restraint and Seclusion", TX.7.1.3.2.4, 1996 Accreditation Manual for Hospitals, Volume 1, Joint Commission on Accreditation of Healthcare Organizations, applies to all organizations accredited under the 1996 AMH, Volume 1, the Comprehensive Accreditation Manual for Ambulatory Care and the Accreditation Manual for Mental Health, Chemical Dependency, and Mental Retardation Developmental Disabilities. The application of these standards, along with public awareness, and health care provider training, have contributed significantly to ensuring that the least restrictive restraint is used and that restraints are used only when needed for proper medical treatment and that their use is under appropriate supervision.

In our experience, the most significant problems involving restraints are not due to design or materials used, but rather are attributed to misuse or misapplication.