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K963457 OCT - 9 1996

TAB F: 510(k) Summary of Safety and Effectiveness

Name, address, phone and fax numbers for person submitting the 510(k) notification:

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Contact person: Arnold Silverman

Date summary was prepared: August 27, 1996

Device name:

Trade name:	Sleeper Jacket, Houdini Safety Sleeper
Common name:	Bed Safety Restraint Jacket
Classification name:	Protective Restraint

Predicate device:

Sleeper Jacket and Houdini Safety Sleeper marketed by Skil-Care Corporation.

Device Description:

Sleeper Jacket: A polyester upper body, jacket-style garment. It has short sleeves, a brass back zipper, 1 1/8-inch-wide- polyester webbing ties sewn across the waist. Each webbing end is terminated with a metal clip that secures to the bed frame. The webbing criss-crosses in front of the patient to allow him/her to roll from side to side while sleeping in bed. The edges of the garment are finished with bias cut binding in a color that corresponds to the garment size as described on package insert. The device has instructions that show how it can be applied in both the bed and the wheelchair.

Houdini Safety Sleeper: Has the same features as the Sleeper Jacket with the addition of a 1 1/2-inch-wide strap sewn to the back of the garment. The strap is brought between the patient's legs and secured in front of the garment. The purpose of this strap is to prevent the patient from sliding down in the bed or wheelchair.

Indications for use: K963457

The Sleeper Jacket and the Houdini Safety Sleeper are intended for patients who require restraint while in bed or in the wheelchair and who easily remove standard vest-style and poncho-style restraints.

The Houdini Safety Sleeper is recommended for patients who slide or move toward the foot of the bed or who slide off the wheelchair seat.

Comparative information:

The device (devices) used for comparative purposes is (are) currently marketed as described in this submission. Device (devices) is (are): Sleeper Jacket and Houdini Safety Sleeper.

These devices are currently exempt from 510(k) Premarket Notification Procedures and Good Manufacturing Practice Regulations and are legally marketed by Skil-Care Corporation as of the date of this submission. Skil-Care Corporation has been marketing and commercially distributing these devices for approximately 18 years.

The difference from our currently marketed devices are that the labeling will be changed to incorporate many of the suggestions in FDA's draft document, "Guidance on the Content of Premarket Notification [510(k)] Submissions for Protective Restraints.

The use of all patient restraints in nursing homes are subject to Health Care Financing Administration's Regulations which prohibit the use of any restraint, physical or chemical, imposed for the purpose of discipline or convenience. Further, most health care facilities are accredited. HCFA rules governing appropriate use and accreditation standards for device use and personnel training provide the control necessary to ensure that the devices are used correctly. 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, that restraints are used only when needed for proper medical treatment, and that their use is under appropriate supervision.