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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:	Roll Belt
Common name:	Bed Safety Belt
Classification name:	Protective Restraint

Predicate device:

Roll Belt marketed by Skil-Care Corporation.

Device Description:

The Roll Belt has a cotton duck pad approximately 26 1/2 inches in length. At its narrowest end, the pad is approximately 6 1/2 inches wide, and at its widest end it is approximately eight inches wide. A 1 1/2-inch-wide, 88-inch-long strap made of polyester webbing is stitched to each end of the cotton duck pad. The wide end has a slot that is approximately 6 1/2 inches long and 1 1/2 inches wide. The webbing from the narrow end is inserted through the slot on the wide end, thereby closing the belt while it encircles the patient's waist. The straps criss-cross in front of the patient permitting him/her to roll from side to side. Both straps are secured to the bed frame. The edges of the device are finished with a bias cut binding.

Indications for use:

The Roll Belt is intended for the patient who requires a safety belt while in bed and who requires a reminder not to leave the bed without assistance.

Comparative information:

The device (devices) used for comparative purposes is (are) currently marketed as described in this submission. Device (devices) is (are): Roll Belt.

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.