Skil-Care CORPORATION

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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:	Safety Poncho, Shoulder Strap Poncho
Common name:	Same
Classification name:	Wheelchair Accessory

Predicate device:

Safety Poncho and Slider Poncho marketed by Skil-Care Corporation.

Device Description:

Safety Poncho: A poncho-style, upper body device made from either woven polyester or polyester mesh. A waist strap secures the device to the wheelchair kickspurs. The strap is 1 1/8-inch-wide polyester webbing. The edges of the garment are finished with a bias cut binding, the color of which corresponds to a size chart included on the package insert. The device is intended for wheelchair use only.

Shoulder Strap Poncho: The Shoulder Strap Poncho has the same configuration as the above with the addition of a strap sewn on the shoulder area. This strap ties to the wheelchair pushhandles to provide posture support. Strap is 1 1/8-inch-wide polyester webbing.

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Indications for use:

The Safety Poncho is used for restraint.

The Shoulder Strap Poncho provides restraint and posture support.

Comparative information:

The device (devices) used for comparative purposes is (are) currently marketed as described in this submission. Device (devices) is (are): The Safety Poncho and the Shoulder Strap Poncho.

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.