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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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Date summary was prepared: August 18, 1996

Device name:

Trade name:	Sleeved Jacket and Sleeved Jacket with Slider Control
Common name:	Same
Classification name:	Wheelchair Accessory

Predicate device:

The Sleeved Jacket and Sleeved Jacket with Slider Control currently marketed by Skil-Care Corporation

Device Description:

Sleeved Jacket: The sleeved jacket is a polyester upper body garment, designed to be worn over clothing, with short sleeves, a brass back zipper, and 1 & 1/8 inch polyester webbing ties sewn across the back at the shoulder area and across the front at the waist. The ties are tied to the wheelchair push handles and kick spurs, respectively, to provide patients with postural support. The edges of the garment are finished with bias cut binding in a color to correspond with the garment size as described in the insert labeling.

Sleeved Jacket with Slider Control: The Sleeved Jacket with Slider Control has the same features as the sleeved jacket with the addition of a crotch pad sewn to the bottom center front. The pad is lined with ¼ inch polyurethane foam and has a 1 & 1/8 inch polyester webbing strap sewn on that is either placed directly under the patient or under the seat of the wheel chair and secured to the wheelchair cross brace to prevent the patient from sliding down.

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Indications for Use:

The *sleeved jacket* is intended for patients who require posture support while seated in a wheelchair.

The *sleeved jacket with slider control* is intended for patients who require posture support and additional support to prevent sliding forward while seated in a wheelchair.

Both are intended for patients who have a history of removing vest-style and poncho-style restraints.

Comparative information:

The devices used for comparative purposes are the Sleeved Jacket and Sleeved Jacket with Slider Control , currently marketed and as described in this submission.

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 manufacturing and commercially distributing these devices for approximately ten 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.