Skil-Care
CORPORATION

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

K963459

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:	Support Vest
Common name:	Same
Classification name:	Wheelchair accessory

Predicate device:

Support Vest marketed by Skil-Care Corporation

Device Description:

The Support Vest is a sleeveless, upper body device that has a poncho-style front bib and vest-style rear wings. These wings have 1 1/8-inch-wide polyester webbing sewn to them and brought around to the front of the device, and passed through two slots on the front bib. This closes the vest and causes the wings to criss-cross over the patient's middle chest thus providing posture support. The webbing secures to the wheelchair kickspurs or to the bed frame. The device is edged in bias cut binding in colors that correspond to a size chart included on the package insert. The device is intended for use in the bed or wheelchair.

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Indications for use:

The Support Vest is intended to provide restraint and upper body support for patients in wheelchairs and restraint for patients in bed.

Comparative information:

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

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 five 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.