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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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Device name:

<u>Trade name:</u>	Double Support Poncho, Slider Poncho
<u>Common name:</u>	Same
<u>Classification name:</u>	Wheelchair Accessory

Predicate device:

Double Support Poncho and Slider Poncho marketed by Skil-Care Corporation.

Device Description:

*Double Support Poncho:* A poncho-style, upper body device made from either woven polyester or polyester mesh. A chest strap is used to provide upper body posture support. A waist strap secures the device the device to wheelchair kickspurs. All straps are 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. Device is intended for wheelchair use only.

*Slider Poncho:* The Slider Poncho has the same configuration as the above with the addition of a crotch pad sewn to the bottom center front. The pad is lined with 1/4 inch polyurethane foam and has a 1 and 1 1/8 inch strap sewn on that is either placed directly under the patient or under the wheelchair seat and secured to the wheelchair cross brace to prevent the patient from sliding down.

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Indications for use:

The Double Support Poncho is used for restraint and to provide upper body posture support.

The Slider Poncho provides restraint, posture support, and slider control.

Comparative information:

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