

**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>	Econo Belt
<u>Common name:</u>	Wheelchair Safety Belt
<u>Classification name:</u>	Wheelchair Accessory

Predicate device:

Econo Belt marketed by Skil-Care Corporation.

Device Description:

*The Econo Belt* is a two-inch-wide, six-foot-long wheelchair safety belt made from nylon webbing. Both ends have sewn loops which can be adjusted in size by means of metal slider buckles. The belt is positioned over the patient's waist, criss-crossed behind the wheelchair, and looped over the kickspurs. It is designed for wheelchair use only.

Indications for use:

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

**Comparative information:**

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