Skil-Care CORPORATION
167 Saw Mill River Road, Yonkers, New York 10701
(914) 963-2040
(800) 431-2972
FAX (914) 963-2567

K963449

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

OCT - 7 1996

Name, address, phone and fax numbers for person submitting the 510(k) notification:

Arnold Silverman, President
Skil-Care Corporation
167 Saw Mill River Road
Yonkers, NY 10701
Phone: 1-914-963-2040
Fax: 1-914-963-2567

Contact person: Arnold Silverman

Date summary was prepared: August 27, 1996

Device name:

Trade name:	Pelvic Holder
Common name:	Same
Classification name:	Wheelchair Accessory

Predicate device:

Pelvic Holder marketed by Skil-Care Corporation.

Device Description:

The Pelvic Holder is a diaper-shaped device made from either woven polyester or polyester mesh. The device fits between the patient's legs and is secured by webbing around the waist. Webbing is 1 1/8-inch-wide polyester and secures to the wheelchair. The purpose of the device is to prevent patient from sliding down in the wheelchair. The edges are finished with bias cut binding that corresponds to a size chart included on the package insert. The device is intended for wheelchair use only.

Indications for use:

The Pelvic Holder is intended for patients who require both slider control and restraint while in the wheelchair.

Comparative information:

K963449

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

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.