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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>	Padded Mitts, Finger Separator Padded Mitts, Rigid Palm Padded Mitts
<u>Common name:</u>	Same
<u>Classification name:</u>	Protective Restraint

Predicate device:

Padded Mitts, Padded-Plus Mitts, Finger Separator Padded Mitts, and Rigid Palm Padded Mitts marketed by Skil-Care Corporation.

Device Description:

Padded Mitts are constructed from woven polyester that encloses a 3/4-inch-thick foam palm pad. A top piece of polyester mesh is sewn on the mitts to prevent heat build-up. The mitts have a 1 1/4-inch-wide polyester wrist strap that secures by means of a metal buckle. The underside of the mitt cuff has a loop through which a 44-inch-long looped strap passes. This strap is used to secure the patient's hand/arm range of motion. The outer edges are finished with a bias cut binding. All straps are made of polyester webbing.

Padded-Plus Mitts are identical to the above except that the foam used for the palm pad is two-inches-thick.

Finger Separator Padded Mitts are identical to Padded-Plus Mitts except that the polyester mesh top piece is stitched to the polyester woven fabric in a such a way as to form finger channels.

Finger Separator
Rigid-Palm Padded Mitts are identical to the Padded Mitts except that they have a pocket on the bottom side which contains a 6mm pvc insert. This rigid insert, which removes for laundering, is used for patients who require an additional barrier to prevent against grasping at feeding and naso-gastric tubes.

Indications for use:

Padded Mitts, Padded-Plus Mitts, Rigid Palm Padded Mitts, and Finger Separator Padded Mitts are intended for patients who remove bandages and dressings, pick and scratch at wounds, grasp and pull out feeding and naso-gastric tubes.

Rigid Palm Padded Mitts have a rigid insert and are intended for patients who require an additional barrier to prevent grasping.

Finger-Separator Padded Mitts have finger channels that help to control hand contracture.

Comparative information:

The device (devices) used for comparative purposes is (are) currently marketed as described in this submission. Device (devices) is (are): Padded Mitts, Padded-Plus Mitts, Rigid-Palm Padded Mitts, and Finger Separator Padded Mitts.

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.