

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>	Reusable Limb Holder, Disposable Limb Holder, Quik-Cuff Limb Holder
<u>Common name:</u>	Limb Holder
<u>Classification name:</u>	Protective Restraint

Predicate device:

Reusable Limb Holder, Disposable Limb Holder, and Quik-Cuff Limb Holder marketed by Skil-Care Corporation.

Device Description:

Disposable Limb Holder (Synthetic Sheepskin-Double Tie): These limb holders have a 2 1/2-inch-wide by 12-inch-long synthetic cuff to which is sewn a 19-inch-long wrist strap. The wrist strap is 1 1/8-inch-wide polyester webbing. It is terminated with a 1 1/4-inch-wide metal buckle. Approximately 2 1/2 inches back from the buckle a 102-inch-long strap (doubled to form two 51-inch-long sections) is sewn to the wrist band. Just beyond the point where this strap is attached, a one-inch-wide, seven-inch-long strip of Velcro loop material is sewn to the cuff. A 2 1/2-inch-long Velcro hook tab is stitched to the same end of the cuff as the buckle. The Velcro hook and loop position the cuff on the wrist or ankle, the wrist strap and buckle secure the device. Sold in pairs.

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Disposable Limb Holders (Synthetic Sheepskin-Single Tie): Identical to the above except that they have a single 51-inch-long strap sewn to the wrist strap.

Disposable Limb Holders (Foam-Double Tie): Identical in construction to the Disposable Limb Holders (Synthetic Sheepskin-Double Tie) except that the cuff is made from 1/4-inch-thick polyurethane foam back with Velcro loop material.

Disposable Limb Holders (Foam-Single Tie): Identical to above except that they have a single 51-inch-long strap sewn to the wrist strap.

Reusable Synthetic Sheepskin Limb Holders: These limb holders have a 2 1/2-inch-wide, 12-inch-long synthetic sheepskin cuff to which is sewn a 19-inch-long, 1 1/8-inch-wide polyester wrist strap. The wrist strap is terminated with a metal buckle. A polyester strap of 1 1/8 inches in width is stitched to the wrist band approximately 2 1/2 inches beyond the buckle. This strap is 102-inches-long and is doubled to form two 51-inch-long sections.

Quik-Cuff Limb Holders: These have a 2 1/2-inch-wide, 12-inch-long synthetic sheepskin cuff to which is attached a 19-inch-long, one-inch-wide Velcro backstrap that includes a one-inch-wide Delrin d-ring through which the Velcro is secured. A single, 51-inch long strap is stitched to the cuff and the backstrap approximately at the center of the cuff.

Indications for use:

The Reusable Limb Holders, Disposable Limb Holders, and Quik Cuff Limb Holders are intended for patients who require limitations placed on their hand and leg movement.

Comparative information:

The device (devices) used for comparative purposes is (are) currently marketed as described in this submission. Device (devices) is (are): The Disposable Limb Holder, Reusable Limb Holder, and the Quik-Cuff Limb Holder.

These devices are currently exempt from 510(k) Premarket Notification Procedures and Good Manufacturing Practice Regulations and are legally marketed by Skil-Care

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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.