

510(K) Summary

K96-3489

Smith & Nephew DonJoy Inc.

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Smith & Nephew

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K. SUMMARY OF SAFETY AND EFFECTIVENESS

The Safety Poncho, Slider Poncho and the Pelvic Holder are intended for use to assist cooperative patients who require minimum support in wheelchair. The devices are labeled for prescription use and are not intended for lay use. These devices are vest and pelvic holder style wheel chair accessories used to assist cooperative patients who require minimum support in a wheelchair. These devices are made of polyester, cotton, nylon and vinyl configured into either a mesh or weave substrate. Each device utilizes straps for securing (tie) the patient in place. These devices have been commercially distributed for over ~~four~~ years and have not been associated with an MDR type complaint.

Smith & Nephew DonJoy, Inc.

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D Miller 10-31-96

Dan W. Miller

8-28-96

Dan W. Miller
Director of Regulatory Affairs and
Quality Assurance

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