

510k Summary

K96-3492

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Smith & Nephew DonJoy Inc.

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Smith + Nephew

K. SUMMARY OF SAFETY AND EFFECTIVENESS

The Economy Restraint, Jacket Restraint, Two Piece Vest Restraint, Safety Vest and Hand Control Mitt 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, jacket and mitt style restraints used to restrain patients in a wheelchair or bed. These devices are made of polyester, cotton, nylon and polyethelen 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~~ + 20 years and have not been associated with an MDR type complaint.

Smith & Nephew DonJoy, Inc.

Dan W. Miller 8-28-96

Dan W. Miller
Director of Regulatory Affairs and
Quality Assurance

D. Miller
10-3-96
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DONJOY.