

510(k) Summary

K 96-3490

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Smith & Nephew DonJoy Inc.

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Smith & Nephew

K. SUMMARY OF SAFETY AND EFFECTIVENESS

These devices are Universal Gait Belt, Wheelchair Belt, Foam Limb Restraint, Double Buckle Limb Restraint, Comfort Safety Belt, Comfort Slider Belt, Universal Roll Belt and belt style restraints used to restrain patients in a wheelchair or bed. The devices are labeled for prescription use and are not intended for lay use. 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~~ two years and have not been associated with an MDR type complaint.

*D Miller*  
10-31-96  
K963490

Smith & Nephew DonJoy, Inc.

*Dan W. Miller* 8-28-96

Dan W. Miller  
Director of Regulatory Affairs and  
Quality Assurance

