



# Posey Company

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K963411

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## SAFETY AND EFFECTIVENESS SUMMARY

NOV 19 1996

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Michael Keefe  
General Manager  
August 30, 1996  
Revised: November 18, 1996

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Reference Number: K963411

Trade Name: Posey® Laptop Trays  
Common Name: Laptop Trays  
Classification Name: Protective Restraints

The devices included in this 510(k) submission provide anterior postural support. The products are closed around the wheelchair by hook and loop straps. An optional strap can be secured behind the patient to prevent the tray from being pushed forward. If the patient cannot easily self release the product, it may be considered a restraint.

These products are intended to provide postural support and a surface for activities.

The devices used for comparative purposes are identical to the laptop trays as described in this submission and produced or sold by the J.T. Posey Co. This premarket submission is submitted in response to the agency's final rule published on March 4, 1996 in the Federal Register 21 CFR 880 and 21 CFR 890 Medical Devices, Protective Restraints - Revocation of Exemptions from 510(k) Pre-market Notification Procedures and Current Good Manufacturing Practice Regulation. The June 13, 1996 Meeting Minutes, HIMA Body Holder Task Force and FDA CDRH established the rationale for which devices would be used for comparison:

*"Predicate device*

FDA indicated that it would be appropriate for manufacturers to reference their current products as legally marketed devices for comparison purposes in their submissions. It would also be appropriate to reference any approved 510(k)s that manufacturers have submitted for their products."

The laptop trays are currently exempt from 510(k) Premarket Notification Procedures and Good Manufacturing Practice Regulations and are legally marketed by JT Posey Co. as of the date of this submission, August 30, 1996. The limb holders have been manufactured and in commercial distribution for up to 20 years.