



Posey Company

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K963409

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SAFETY AND EFFECTIVENESS SUMMARY

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Michael Keefe
General Manager
August 30, 1996
Revised: November 13, 1996

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Reference Number: K963409

Trade Name: Posey[®] Hugger
Common Name: Hugger
Classification Name: Wheelchair Accessory

The devices included in this 510(k) submission provide anterior postural support. The products are inserted into the arms of the wheelchair compressing the foam and releasing it once in position. 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 huggers as described in this submission and produced or sold by the J.T. Posey Co. 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 huggers are currently exempt from 510(k) Premarket Notification Procedures and Good Manufacturing Practice Regulations and are **legally marketed** by JT Posey Company as of the date of this submission, August 30, 1996.