

K963674

JAN 10 1997

LUMEX Medical Products Inc.
A Fuqua Enterprises Company Inc.

LUMEX_{AIR}

1.0 510(k) Summary

Submitter: Lumex Medical Products, Inc.
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Classification Name: Low air loss zero pressure mattress flotation therapy -89IOQ
(890.5170)

Common or Usual Name: Portable powered low air loss flotation therapy mattress.

Proprietary Name: LUMEX_{AIR}

Establishment Registration Number: 2427360

Classification: Class II

Performance Standard: None established under section 514

Labeling/Promotional Material: See enclosed Table of Contents

Substantial Equivalence: This product is similar in design, composition and function to the Orthoderm HC System® (350513) manufactured by Bio Clinic a division of Sunrise Medical, as well as, the Akrotech 4000® manufactured by Lumex Medical Products and as well as, the Plexus 3000® manufactured by Plexus Medical remanufactured and distributed by Lumex Medical Products Incorporated under the ALTAIR product line. Please note that both the LUMEX/Plexus 3000® and the LUMEX/Akrotech 4000® have already received 510(k) status and evidence of this is copied in Appendix IV, reference K952610, dated September 7, 1995, by Timothy A. Ulatowski, Acting Director, Pilot Division; reference K923977, dated September 4, 1992, by Paul R. Beninger, M.D., Acting Director, General and Restorative Devices Division respectively.