

JUL 18 1996

K962123

510(k) Summary

AkroTech 4000T Kinetic Turning Low Air Loss (LAL) System

Lumex

LUMEX

A Fuqua Enterprises Company

510(k) Summary

Submitter: Lumex Medical Products, Inc.
100 Spence St.
Bay Shore, NY 11706
Phone (516)-273-2200
Fax (516)-273-2408

Contact Person: Joseph Zanetti
Divisional Quality Assurance Manager

Date Summary Prepared: 5-22-96

Classification Name: Low air loss mattress flotation therapy - 89IOQ
(890.5170)

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

Trade / Proprietary Name: AkroTech 4000T Kinetic Turning Low Air Loss System

Establishment Registration: 2427360 (Lumex Div. of Lumex, Inc.)
1318909 (Site of manufacture)

Classification: Class II

Performance Standards: None established under section 514

Labeling / Promotional Materials: See attachments

Substantial Equivalence: This product is similar to the AkroTech 4000
product submitted by Lumex Div. of Lumex, Inc.
approved by the FDA reference number K923977.

510(k) Summary (cont'd)

The device, brand name AkroTech 4000T Kinetic Turning Low Air Loss (LAL) System, is substantially equivalent to the AkroTech 4000 Dynamic Low Air Loss System (K923977).

Both Low Air Loss support systems consist of two operating components:

1. The electromechanical, computer controlled Air Control unit (ACU)
2. The Air Floatation Mattress.

Both Systems promote pressure reduction by redistributing patient weight over a surface area / medium or by shifting patient weight from one area to another. As with the AkroTech 4000, the AirBed Corporation (1240 S. Claudina St., Anaheim, CA 92805) is responsible for manufacturing the AkroTech 4000T ACU and Lumex (100 Spence St., Bay Shore, NY 11706-2290) is responsible for manufacturing the 4000T air flotation mattress and marketing the product. AirBed is registered with the FDA (#2029170) as is Lumex (#2427360). AirBed Corporation operates under operator #9010115.

COMPARISON OF OVERALL FEATURES OF AKROTECH 4000 DYNAMIC SYSTEM TO AKROTECH 4000T TURNING SYSTEM

FEATURE	AKROTECH 4000 DYNAMIC	AKROTECH 4000T TURNING
Switch	On / Off Toggle	On / Off Toggle
Modality	Firm, Float, CPR, Key Pad Lock, Alarm	Firm, Float, CPR, Key Pad Lock, Alarm
Data Input Control	Up / Down	Up / Down
Input Information	Patient Weight	Patient Weight, Height, Rotation Angle, Time In Angle
Data Feedback	Patient Time In Use, Cumulative Operating Time	Patient Time In Use, Cumulative Operating Time
Air Control Zones	Six	Six
Air Flow Lines	One	One

510(k) Summary (cont'd)

COMPARISON OF ACU FEATURES OF AKROTECH 4000 DYNAMIC SYSTEM ACU TO AKROTECH 4000T TURNING SYSTEM ACU

ACU FEATURE	AKROTECH 4000 DYNAMIC	AKROTECH 4000T TURNING
Computer	Same	Same
Hardware	Same	Same
Blower	Same	Same
Valves	Same	Same
Materials	Same	Same
Overall Dimensions	Same	Same
LCD Display	Same	Same
Key Pad	Same	Same
Labeling	See Attachment	See Attachment
Operator's Manual	See Attachment	See Attachment
Safety	UL544 and CSA Listed	UL544 and CSA Listed
Hose Connections	Locking Collet	Quick Disconnect
Graphic Overlay	Dynamic	Rotational
Computer Program / Software	Dynamic	Rotational

COMPARISON OF MATTRESS FEATURES OF AKROTECH 4000 DYNAMIC SYSTEM MATTRESS TO AKROTECH 4000T TURNING SYSTEM MATTRESS

MATTRESS FEATURE	AKROTECH 4000 DYNAMIC	AKROTECH 4000T TURNING
Air Control Zones	Same	Same
Air Flow Lines	Same	Same
Base	Same	Same
Bottom Cover	Same	Same
Top Cover	Same	Same
Tie Down Straps	Same	Same
Mattress Size	Same	Same
Safety	California # 117, UL544 and CSA Listed	California # 117, UL544 and CSA Listed
Intermediate Comfort Cover	Zipper Closure	Button Closure
CPR Deflate	Manual Release at Head End Only	Manual Release at Both Ends
Air Lines	Colored Extruded Air Hoses	Clear Air Hose with Colored Spirals
Air Cells	18	14