KCI

SEP - 5 1997

510 (k) Summary

K970468

I.	**Name of Device:**	**KinAir IV/Therapulse II (KT Air Bed)**
II.	**Classification Name:**	Bed, Flotation Therapy, Powered (per 21 CFR 890.5170)
III.	**Substantial Equivalence:**	Therapulse, 510(k) No. K875321 KinAir, 510(k) No. 880340 TriaDyne Plus, 510(k) No. 944094

IV. Device Description:

The KinAir IV, Therapulse II (a.k.a. KT Air Bed) device is a pulsating low air-loss support mattress replacement system mounted on a commercially-available Stryker 3000 Acute Care Bed Frame, that also includes a Turn Assist feature. The mattress replacement system itself is essentially of the same general construction as the predicate Therapulse (510(k) No. K875321) and the KinAir (510(k) No. K880340 and the substantially equivalent TriaDyne device (510(k) No. K944094). It consists of the fabric support and the various cushions. The fabric support is a Gore-Tex fabric assembly for supporting and containing the twenty five upper cushions. Two additional inflatable cushions are on the underside of the fabric support, to assist the caregiver when turning the patient. All inflatable cushions are made of a vinyl Gore-Tex fabric to provide a low shear, low friction surface that is washable and durable.

The KinAir IV, Therapulse II Air Bed has two general modes of operation: 1) static, and 2) turn assist, with an optional third mode, pulsation, available only on the Therapulse II. The Display membrane panel mounted on the footboard and in each foot siderail, are used to select the static and pulsing modes. For the static mode, four individually adjustable sections of upper cushions are inflated to support the patient with minimal air pressures. For the pulsing mode, over an adjustable cycle of between 2 1/2 and 40 minutes, some cushions are inflated and deflated more or less than others in order to alternate the pressures supporting the patient. The cycle repeats continuously until the pulse mode is deactivated.

The Turn Assist mode is only available on the Home Display membrane panel mounted on the footboard. When the caregiver selects this mode to turn the patient either left or right, either the left or right bladder cushion will inflate and lean the patient approximately 15-20 degrees and stay inflated until the caregiver deactivates the turn assist mode. This feature was added to assist the caregiver when performing routine patient care, such as bathing, bedpan placement, etc.

The blower unit and Air Supply Unit are mounted on the Stryker bed frame, beneath the mattress. They are controlled to achieve the various modes of operation according to user input

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through switches on the membrane panels mounted on the footboard and on the outside of the foot siderails. All user input is accomplished through these membrane panels. The membrane panels with the various settings and displays are illustrated throughout the KinAir IV and Therapulse II Quick Reference Guides.

The Air Supply Unit's warmer is provided to warm air in the mattress for patient comfort. The blower is mechanically and electrically isolated to help prevent injury and reduce noise. The warming element itself is a conventional resistive silicon heater. The warmer actually warms the air in the Air Supply Unit's manifold, and the air then passively warms the patient to the degree selected by the patient's attendant. There are three settings: 1) LOW, 2) MEDIUM and 3) HIGH. At the HIGH setting, the heating element is capable of achieving maximum temperatures of roughly ten degrees Fahrenheit above ambient. Temperature feedback from sensors adjacent to the blower manifold allows for control of such temperatures. This is the same system that was used in the predicates Therapulse and KinAir.

When first inflated, the KinAir IV and the Therapulse II are automatically set in the static mode. Pulsation therapy, available on the Therapulse II, only, when activated, begins alternating pressure between sets of cushions. When pulsation is first activated, the cushion closest to the footboard decreases its pressure, together with every other cushion along the mattress length, while the other pressures are increased. Once the first set of cushions reaches its lowest point and starts to increase, the second set of cushions starts to decrease. The second set reaches its minimum just as the first set reaches its maximum. The cycle then repeats all over again, resulting in a pulsating effect. The minimum cycle time of 2 1/2 minutes is the time it takes for a pulsating cushion to partially deflate and then inflate again.

INTENDED USE OF THE KINAIR IV, THERAPULSE II

The KinAir IV and Therpulse II beds are for supporting bedridden patients in a manner that helps prevent and treat complications of immobility such as skin breakdown and decubitus ulcers. More particularly, it employs a patient supporting mattress overlay having an arrangement of transverse inflatable cushions that can be controlled to provide slowly pulsating pressures beneath the patient, as well as bladders to assist in turning the patient to one side or the other.

INDICATIONS

The KinAir IV and Therapulse II beds are indicated to assist in the prevention and treatment of complications of immobility, especially for patients who would benefit from a pressure relieving surface with the additional optional benefit of pneumatic pulsation.

CONTRAINDICATIONS

Patient conditions for which the application of therapy on the KinAir IV and Therapulse II beds are contraindicated include the following:

- Unstable spinal cord injuries
- Cervical traction

DIFFERENCES BETWEEN CURRENT AND PREDICATE DEVICES

The KinAir IV and Therapulse II are modifications and replacements for the predicate devices KinAir and Therapulse beds. The major modification is the Stryker MPS 3000 frame used for the platform, replacing the Hill-Rom frame.

By using the Stryker MPS 3000 frame, the air components are mounted in the base of the frame, in one enclosure, as opposed to multiple enclosures in the litter and base of the Hill-Rom frame. Other features include:

- retractable bed frame - shortens the bed frame up to 14"
- Trendelenburg/reverse Trendelenburg and Cardiac Chair are controlled from the Head Siderail and Footboard
- Foot end control panel is located at the top of the Footboard as opposed to below the footboard
- Head siderails have patient controls located inside and Nurse controls on the outside
- In-bed scale is built into the frame
- Patient exit alarm system
- Nurse control panels are also located outside of foot siderails.

The low air loss mattress replacement system is essentially the same as the predicates KinAir and Therapulse devices. Design modifications were implemented to facilitate assembly of the bed, removal of the bed after use and cleaning procedures, yet retaining the same functions as the predicate devices. The KinAir IV mattress (blue colored), or the Therpulse II mattress (burgundy colored) can be used on the same modified Stryker MPS 3000 frame.

Comparative Information

	KT AIR BED	KINAIR	THERAPULSE	TRIADYNE PLUS
DIMENSIONS				
Patient Support Surface &Frame	Stryker frame	Hill-Rom Frame	Hill-Rom Frame	Stryker frame
Length	93"	93"	93"	93"
Width	43"	38"	38"	43"
Height to Floor - High	47"	47"	47"	47"
Low	35"	36"	36"	35"
MAX.PATIENT WEIGHT	700 lbs.	300 lbs.	500 lbs.	500 lbs.
PATIENT SURFACE MATERIAL	Gore-Tex	Gore-Tex	Gore-Tex	Gore-Tex
Low Air-Loss Therapy Cushions	Yes	Yes	Yes	Yes
PERCUSSION/ VIBRATION	No	No	No	Yes
ROTATION	No	Yes	No	Yes
Max. Turning Angle	N/A	45	N/A	40
TURN ASSIST	Yes	No	No	No
PULSATION	Optional	Yes	Yes	Yes
WARMED AIR	Yes	Yes	Yes	Yes
MAXIMUM TRENDELENBURG	12	12	12	12
MAXIMUM REVERSE TRENDELENBURG	12	12	12	12
BACKUP BATTERY	Yes / Inverter	Yes / Transport Air	Yes / Transport Air	Yes / Inverter
ELECTRICAL DATA				
Voltage	115 v	120 v	120 v	115 v
Frequency	60 Hz	60 Hz	60 Hz	60 Hz
Max. Leakage	100 microamps	90 microamps	90 microamps	100 microamps

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Mr. William H. Quirk
Director of Regulatory Affairs
Kinetic Concepts, Inc.
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SEP - 5 1997

Re: K970468
KT Air Bed
Regulatory Class: II
Product Code: FNM
Dated: June 5, 1997
Received: June 9, 1997

Dear Mr. Quirk:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K970468

Device Name: KinAir IV, Therapulse II (a.k.a. KT Air Bed)

Indications for Use:

The KinAir IV, Therapulse II Air Bed bed is indicated to assist in the prevention and treatment of the complications of immobility, especially for patients who would benefit from a pressure relieving surface with the additional optional benefit of pneumatic pulsation.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K970468

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)