KCI

510 (k) Summary JAN 16 1998 K972176

I.	**Name of Device:**	**Home Care Bead Bed**
II.	**Classification Name:**	Bed, Air Fluidized Therapy, Powered (per 21 CFR 890.5160)
III.	**Substantial Equivalence:**	FluidAir®, 510(k) No. K881917

IV. Device Description:

The Home Care Bead Bed is designed to provide Air Fluidized Therapy by supporting the patient on a surface of fluidized Microspheres (or "beads"). A large volume of air is forced upward through the microsphere mass causing the beads to behave as a fluid, helping reduce interface pressures while providing a dry patient environment with minimized dehydration. The Home Bead Bed is designed for home health care use allowing easy two-man transportation, installation and serviceability. The Home Bead Bed is a modification of the predicate fluidized bead bed, FluidAir® (by KCI), currently on the market and complies with the weight regulations for mobile and wood floor homes.

The Home Care Bead Bed is comprised of the Head Pedestal (containing the Head Cushion System Control unit), the Foot Pedestal (containing the Power-Controller unit), the Tank unit with the Soft Diffuser, a wooden Floor Board, the Beads, Filter Sheet and the Head Cushion System incorporated into the Cover Sheet.

The Foot Pedestal encloses the Air Supply unit that provides air to the soft diffuser and the Head Cushion System. The Air Supply unit contains similar components used in the FluidAir power unit such as blowers, heat exchanger, thermostat controls, cooling fans and filters. The Power-Control Unit located at the Foot Pedestal (refer to membrane diagram) has an "On/OFF" button and a "Fluidization" knob that allows the care giver to increase or decrease the fluidization. By turning the knob toward "MAX", the blower speed increases and sends more air through the Soft Diffuser thus increasing the fluidization rate. By turning the knob toward "MIN", the blower speed decreases and less air is blown through the diffuser thus decreasing the fluidization rate. The "Temp" knob on the Power-Control Unit allows the care giver to adjust the temperature of the air flowing to the beads. This heating and cooling regulation system is similar to the one used on the FluidAir.

The Head Cushion System consists of a head cushion (consisting of two air bladders) and a knee gatch bladder made of vinyl Gore-Tex® fabric and sewn onto a Gore-Tex® fabric cover sheet, similar to the FluidAir bed cover sheet, and placed atop the Home Care Bead bed. The two head cushion bladders and the knee gatch bladder are controlled by small bore servo valves located in the Head Pedestal. These valves are connected to individual port pins for appropriate control. The top head cushion bladder is operated in a pressure feedback mode, while the bottom head cushion operates only in an ON or OFF mode (no pressure feedback control). The knee gatch valve is plumbed in such a way as to draw air from the bottom head cushion bladder whenever

Mailing:
P.O. Box 659508
San Antonio, Texas 78265-9508
1-800-531-5396 / Fax (210) 308-3998

Corporate:
8023 Vantage Drive
San Antonio, Texas 78230-4726
(210) 524-9000

Manufacturing:
4958 Stout Drive
San Antonio, Texas 78219-4334
(210) 662-9191

the "High" setting is selected. Otherwise, the knee gatch bladder remains deflated. Forty (40) degrees of elevation can be achieved when both head cushions are inflated. The knee gatch bladder provides greater patient positioning when the bottom head cushion is elevated.

The Hand Control has an ON and OFF control for fluidization, and SOFT and FIRM and HIGH and LOW controls for the Head Cushion System. When the Head Cushion System's power is turned ON, the system defaults to the LOW setting of mid-range firmness for the Top Head cushion. The Bottom Head cushion and Knee Gatch cushion remain deflated. The FIRM and SOFT control buttons adjusts the firmness level of the Top cushion. The HIGH control button fully inflates the Bottom Head cushion and the Knee Gatch bladder. The head will elevate to a maximum of 40 degrees, depending on the firmness of the Top Head Cushion. The LOW control button returns the system to the Low setting, which will return the head elevation to approximately 10 degrees. When the Head Cushion System is turned OFF, all cushions in the Head Cushion System are deflated.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 16 1998

Mr. William H. Quirk
Director of Regulatory Affairs
Kinetic Concepts, Inc.
3440 East Houston Street
San Antonio, Texas 78265-9508

Re: K972176
Trade Name: Home Care Bead Bed
Regulatory Class: II
Product Code: INX
Dated: September 23, 1997
Received: October 20, 1997

Dear Mr. Quirk:

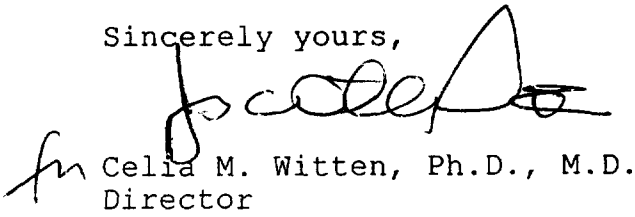
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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

INTENDED USE OF HOME CARE BEAD BED

The Home Care Bead Bed is designed to provide Air Fluidized Therapy that helps prevent and treat complications of immobility such as skin breakdown and decubitus ulcers, while providing minimized dehydration.

The Head Cushion System is an air inflatable cushion system designed to raise a patient's upper body. This cushion system is a replacement to the foam cushion wedges presently available on the FluidAir Bead Bed.

INDICATIONS

The Home Care Bead Bed is indicated for patients who would benefit from advanced pressure relief and a dry patient environment. Particular classes of such patients include (among others), victims of the following:

- Pressure Ulcers - especially draining wounds
- Skin Flaps and Grafts
- Burns
- Acute Exfoliative Dermatitis
- Oncology:
    - Aids in pain relief
    - Reduces risk of Pathological Fractures

CONTRAINDICATIONS

Patient conditions for which the application of Air Fluidized Therapy on the Home Care Bead Bed is contraindicated include:

- Acute or Unstable Spinal Cord Injury
- Traction

Prescription Use X
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K972176

Prepared by: J. Harbour
Kinetic Concepts, Inc.
P.O. Box 659508
San Antonio, TX 78265

Date Prepared:
June 1, 1997