

**510(K) SUMMARY**  
**Prepared October 21, 1997**

K953243

[1] **Submitter's Name:** Kinetic Concepts, Inc.  
**Address:** 8023 Vantage Drive  
San Antonio, TX 78230  
**Telephone Number:** 210/255-4545  
**Contact Person:** William II. Quirk

OCT 23 1997

[2] **Device Name:** BariAir  
**Trade or Proprietary Name:** BariAir  
**Common or Usual Name:** Low Air Loss Bed  
**Classification Name:** Bed, AC-Powered, Adjustable Hospital

[3] **Predicate Device:** BariKare Plus

[4] [6] **Device Description & Technological Comparison.**

BariAir is a bariatric patient care system that combines the flexible patient-positioning capabilities of the predicate device (BariKare Plus) with a pressure relieving, dynamic low-air-loss mattress. The BariAir mattress is a three-section air mattress consisting of a series of transverse, inflatable cushions that can be alternately inflated and deflated to provide pulsation therapy, four turning bladders to rotate the patient side to side, and an air bladder beneath the patient chest region cushions to provide vibration/percussion therapy. The BariAir device includes support and caster frames substantially the same as the predicate device.

BariAir also provides continuous lateral rotation therapy, automatically turning the patient, as well as other adjunct therapies such as pulsation and vibration/percussion.

[5] **Intended Use**

The BariAir device is a hospital bed system designed to support patients whose weights exceed standard hospital bed weight limitations or whose weight and size cannot be managed by the nursing staff. BariAir combines the flexible patient-positioning capabilities and built-in scale feature of the predicate device with a pressure relieving, low-air-loss mattress system that is designed to help in the prevention of skin breakdown and decubitus ulcers caused by prolonged patient immobility.

The BariAir bed is indicated for patients weighing up to 850 pounds to aid in the prevention and treatment of complications of immobility. Particularly:

- patients who would benefit from a pressure relieving surface with the additional benefits of pulsation, percussion and/or continuous or regular turning from side to side.
- patients whose body weight and size pose a significant risk of injury to the patient or nursing staff during the performance of routine nursing care procedures.

BariAir is contraindicated for patients with unstable spinal cord injuries.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20856

Mr. William H. Quirk  
Director, Regulatory Affairs  
Kinetic Concepts, Incorporated  
P.O. Box 659508  
San Antonio, Texas 78265-9508

OCT 23 1997

Re: K955243  
Trade Name: BARIAIR (w/o the remote hand controller)  
Regulatory Class: II  
Product Code: FNM  
Dated: August 14, 1997  
Received: August 18, 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

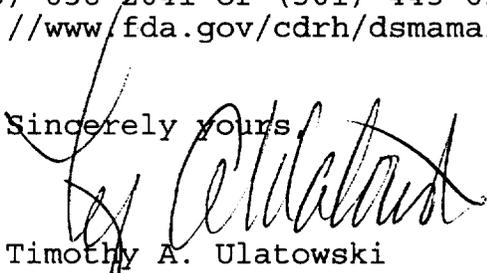
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Product Radiation Control provisions, or other Federal laws or regulations.

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) 594-4618. 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/dsmmain.html>".

Sincerely yours,



Timothy A. Ulatowski  
Director  
Division of Dental, Infection Control  
and General Hospital Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510(k) Number (if known): K955243

Device Name: BARIAIR

Indications for Use:

The BariAir bed is indicated for patients weighing up to 850 pounds to aid in the prevention and treatment of complications of immobility. Particularly:

- patients who would benefit from a pressure relieving surface with the additional benefits of pulsation, percussion and/or continuous or regular turning from side to side.
- patients whose body weight and size pose a significant risk of injury to the patient or nursing staff during the performance of routine nursing care procedures.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Patricia Cascone

(Division Sign-Off)  
Division of Dental, Infection Control,  
and General Hospital Devices

510(k) Number K955243

Prescription Use \_\_\_\_\_  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)