

K 954320

# Summary

JUL 18 1997

## Introduction

Modified PediKair is a critical care bed with an air mattress for supporting bedridden pediatric patients in a manner that helps prevent and treat complications of immobility such as skin breakdown and decubitus ulcers. The air mattress consists of a series of transverse, inflatable cushions that can be alternately inflated and deflated to provide pulsation therapy (as on the predicate device), an air bladder beneath the patient's chest region to provide vibration/percussion therapy, and left and right turning bladders to rotate the patient side to side. Inflatable support cushions on each side of the patient's head and body keep the patient positioned properly during rotation. PediKair includes the collapsible side rails and removable head and foot rails of the predicate device for maximum and immediate access to the patient—CPR can be performed without the hindrance of rails and without removing the patient from the bed.

## Summary

As with the predicate device, the re-designed PediKair mattress is also a low-pressure air mattress. Low-pressure support mattresses are effective in preventing or reducing the incidence of decubitus ulcers in immobile patients by lowering the pressure on any portion of the body to below capillary pressure (25-35 mmHg).

Modified PediKair also provides kinetic therapy, which is effective in the care management and prevention of decubitus ulcers and in the treatment or mitigation of pulmonary complications caused by prolonged immobility. A continuously rotating surface, similar in concept and design to that of the KCI Pediatric RotoRest P-30 product (510(k) No. K822402), automatically turns the patient 40° (maximum) on one side of the body, to lying on his/her back, to 40° (maximum) on the opposite side of the body. The side support cushions, which automatically inflate when Modified PediKair is in use, and the bed's side rails keep the patient from falling out of the bed while in a rotated position, or while being rotated.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

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

Re: K954320  
Trade Name: Modified Pedikair  
Regulatory Class: II  
Product Code: FNM  
Dated: June 12, 1997  
Received: June 13, 1997

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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 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.

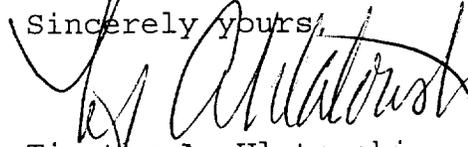
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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.

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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), promotion, or advertising, please contact the Office of Compliance, Promotion and Advertising Policy Staff (HFZ-302) 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 at (301) 443-6597.

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