KCI

K980235

APR - 9 1998

510 (k) Summary

I.	**Name of Device:**	**Inflatable Positioning Cushions with Remote Hand Control**
II.	**Classification Name:**	Patient supports, accessories to Mammographic x-ray system.
III.	**Substantial Equivalence:**	General Purpose T-Foam Pads Scintimammography Prone Breast Cushion Scintimammography Table Overlay Scinti Mammography Positioning Pads

IV. Device Description:

The ImageAir Remote Hand Control is a remote control transmitter, utilizing 4 AA batteries. It is utilized in conjunction with an integrated Infrared receiver, located in the Main Control Panel of the Blower Assembly, to inflate and deflate the air cushions. The Remote Control transmitter incorporates a membrane keypad which provides control over the following functions:

- Torso Strap On/Off
- Head Strap On/Off
- Height Adjust Up/Down
- Roll Adjust Left/Right
- Roll Adjust Level
- Lower All (Patient Exit)

The Blower Assembly incorporates a microprocessor control as an additional safety feature to ensure the valves which regulate air pressure to the various inflatable cushions are operated in the proper sequence. For example, it would be inadvisable to raise or lower the patient when the table locking straps are disengaged. The microprocessor inside the blower box monitors strap status and will not allow the valves which direct air into the height adjustment cushions to be operated until the straps are verified as being locked.

Mailing:
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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

V. Indications

The Inflatable Positioning Cushion with Remote Hand Control is intended to be used on nuclear imaging tables for Scintimammography procedures. The Inflatable Positioning Cushion allows for comfortable, anatomically correct, prone positioning of the patient during Scintimammography.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 9 1998

Judith A. Harbour
Regulatory Affairs
KCI New Technologies, Inc.
P.O. Box 659508
Antonio, Texas 78265-9508

Re: K980235
Remote Hand Control to the Inflatable Positioning Cushion (a.k.a. ImageAir)
Dated: January 20, 1998
Received: January 22, 1998
Regulatory class: II
21 CFR 892.1710/Procode: 90 IZH

Dear Ms. Harbour:

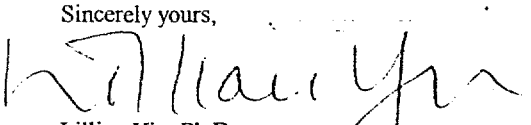
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 requirements, 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) 594-4613. 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/dsma/dsmamain.html".

Sincerely yours,



Lillian Yin, Ph.D.
Director, Division of Reproductive, Abdominal, Ear, Nose and Throat and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K980235

Device Name: Inflatable Positioning Cushions (a.k.a. ImageAir) with Remote Hand Control

Indications for Use:

The Inflatable Positioning Cushion with Remote Hand Control is intended to be used on nuclear imaging tables for Scintimammography procedures. The Inflatable Positioning Cushion (a.k.a. ImageAir) allows for comfortable, anatomically correct, prone positioning of the patient during Scintimammography.

(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 Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K980235

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

(Optional Format 1-2-96)