

27-5715

## 510 (k) Summary

NOV 10 1997

- I. Name of Device:** Inlatable Positioning Cushions
- 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 Inlatable Positioning Cushion is designed to be used on a standard nuclear imaging table with cradle dimensions of 80" long by 14" wide, such as the SPECT Table manufactured by Medical Imaging Electronics. The Inlatable Positioning Cushion is comprised of a Head Section and Abdominal Section, containing foam cushions and inflatable cushions, and a Lower Body Section of foam cushions. The cushions are secured to the nuclear imaging table with Velcro straps and inflatable straps that wrap underneath the table. The blower for the inflatable cushions is in a separate enclosure that can hang at the end of the nuclear imaging table or sit on the floor.

**V. Indications**

The Inlatable Positioning Cushion device is intended to be used on nuclear imaging tables for Scintimammography procedures. The Inlatable Positioning Cushion device allows for comfortable, anatomically correct, prone positioning of the patient during Scintimammography.

**VI. Comparative Information**

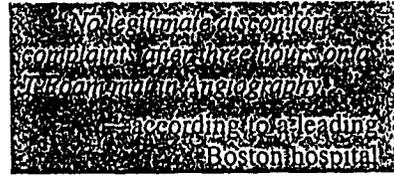
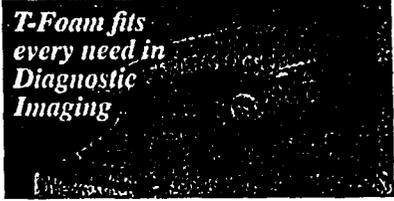
See attached Promotional Material.

# AliMed Diagnostic Imaging Products

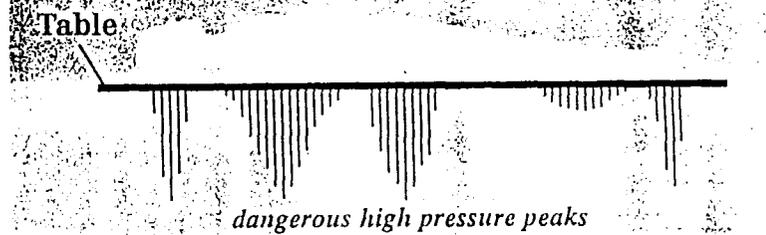
## 20 new replacement table pads!

- Substantially reduces lower back pain during long procedures!
- Helps reduce patient movement—you work faster!
- Radiolucent and artifact free

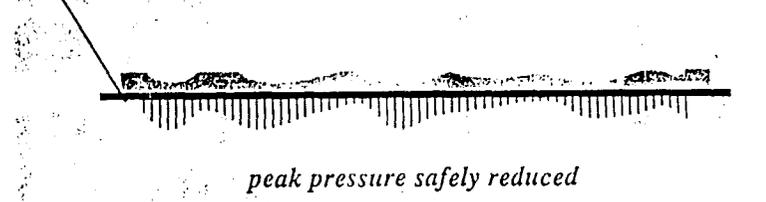
T-Foam represents a unique breakthrough in pressure distribution! Immobilized patients often experience lower back discomfort and painful pressure during long procedures, such as cardiac cath, angiographies and hypertensive IVPs. The lumbar region is not supported well by ordinary table pads. Patients react by moving to relieve the pain and pressure—blurring images and complicating procedures. T-Foam precisely molds to each patient's contours to provide a total contact resting surface—eliminating lower back discomfort and painful pressure. Patient comfort soars. Procedures are completed quickly and efficiently.



Pressure peaks cause pain and movement



T-Foam™ Pad Safe, distributed pressure



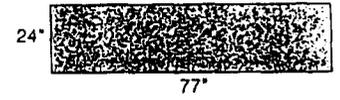
T-Foam pads are radiolucent. They are 1 1/2" thick and are covered with blue nylon cover with water resistant seams.

**SAVE UP TO 50%  
OVER OEM PRICES—  
FOR A BETTER PRODUCT!**

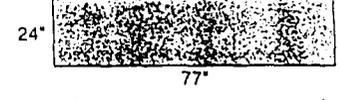
### General Purpose T-Foam Pads



#E9-213 Narrow X-ray, 1 1/2" \$299.95 ea



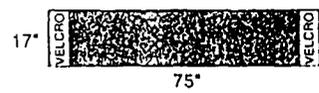
#E9-211 Thick X-ray, 2" \$399.95 ea



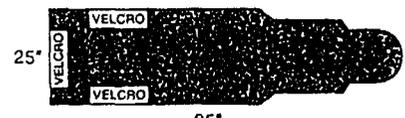
#E9-210 Standard X-ray, 1 1/2" \$349.95 ea



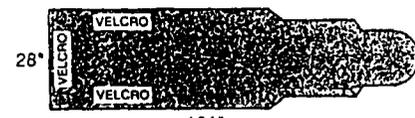
#E91-370 CGR Angix 80 U Cardiac Cath Table \$465.00 ea



#E9-677 GE 9800 C.T. Scanner \$299.95 ea



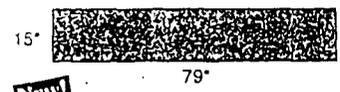
#E9-546 GE LU \$499.95 ea



#E9-545 GE Omega \$599.95 ea



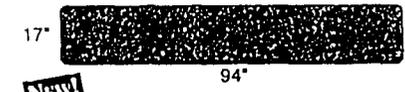
#E920177 GE Omega III \$644.00



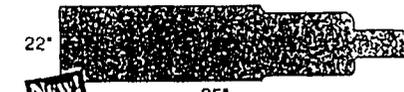
#E920176 Nuclear Medicine Spect \$299.95 ea



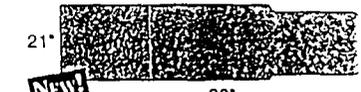
#E920161 Phillips EP 94 \$362.00 ea



#E920162 Phillips EP 94 \$312.00 ea



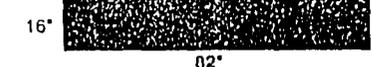
#E920159 Phillips PB134 \$439.00 ea



#E920158 Phillips SR134A \$433.00



#E920175 Nuclear Medicine Spect \$299.95 ea



#E920160 Phillips EP 94 \$362.00 ea



#E920163 Phillips PB134 \$439.00 ea



#E920157 Phillips SR134A \$433.00



#E920156 Phillips EP 94 \$312.00 ea

<p><b>NEW!</b> #E920176 Nuclear Medicine Spect \$299.95 ea 13½" 71"</p>	<p><b>NEW!</b> #E920161 Phillips EP 94 \$362.00 ea 16" 82"</p>	<p><b>NEW!</b> #E920162 Phillips EP 94 \$312.00 ea 16" 89"</p>	<p><b>NEW!</b> #E920159 Phillips PB134 \$439.00 ea 21½" 79"</p>	<p><b>NEW!</b> #E920158 Phillips SR134A \$453.00 25" 86"</p>
<p>#E9-694 Phillips Tomoscan \$299.95 ea 17" 4½" 30½" 84"</p>	<p><b>NEW!</b> #E920157 Picker 1200X CT \$256.00 ea 14" 74"</p>	<p>#E91-237 Picker CT \$399.95 ea 16" 82"</p>	<p>#E91-103 Siemens Koordinat Angio \$499.95 ea 22½" 60"</p>	<p><b>NEW!</b> #E920173 Siemens Koordinat \$550.00 112"</p>
<p><b>NEW!</b> #E920174 Siemens Koordinat 3DIII \$365.00 ea 24" 92"</p>	<p><b>NEW!</b> #E920171 Siemens Somatom Plus \$200.00 ea 21" 94"</p>	<p><b>NEW!</b> #E920172 Siemens Somatom Plus \$256.00 ea 28" 94"</p>	<p><b>NEW!</b> #E920175 Spectrum Angio \$265.00 ea 24" 96"</p>	<p><b>NEW!</b> #E920166 Toshiba Cardiac Cat \$612.00 13" 72"</p>
<p><b>NEW!</b> #E920167 Toshiba CAT 150/250 \$464.00 ea 30" 84"</p>	<p><b>NEW!</b> #E920168 Toshiba Cath Lab \$415.00 ea 28" 98"</p>	<p><b>NEW!</b> #E91-104 Toshiba Cath Lab \$499.95 ea 30" 5½" 18" 84"</p>	<p><b>NEW!</b> #E91-602 Toshiba Special Procedure \$499.00 ea 18½" 80"</p>	<p>#E920169 Toshiba TCT 500S \$183.00</p>
<p>#E91-570 XRE \$499.95 ea</p>	<p>#E920163 XRE-ADC \$576.00 ea</p>	<p>#E920164 XRE-ADC \$642.60 ea</p>	<p>#E920165 XRE #8844AO \$311.00 ea</p>	

*If you don't see your pad above, we'll make one to your specifications!*

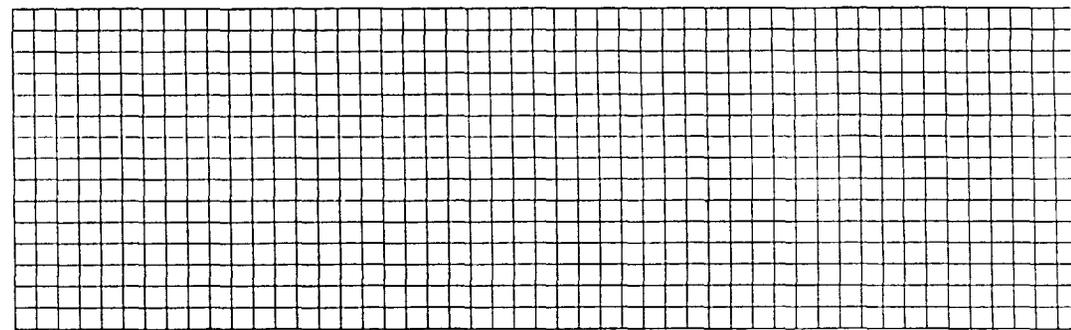
**Custom Table Pad Order Form**

Fill in the information below and provide either a dimensional sketch on the graph form at right or a full-scale tracing of the original pad. Include location and description of any Velcro® fasteners or zippers desired.

MAIL TO:  
Custom Table Pad Department  
AliMed, inc.  
297 High Street  
Dedham, MA 02026

OR FAX TO: (617) 329-8392

Each square=2"



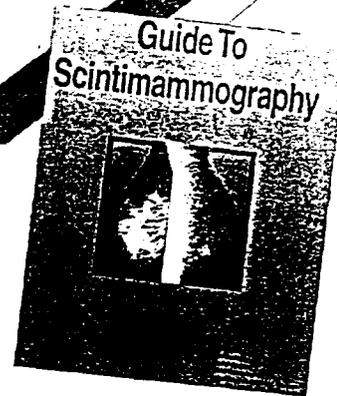
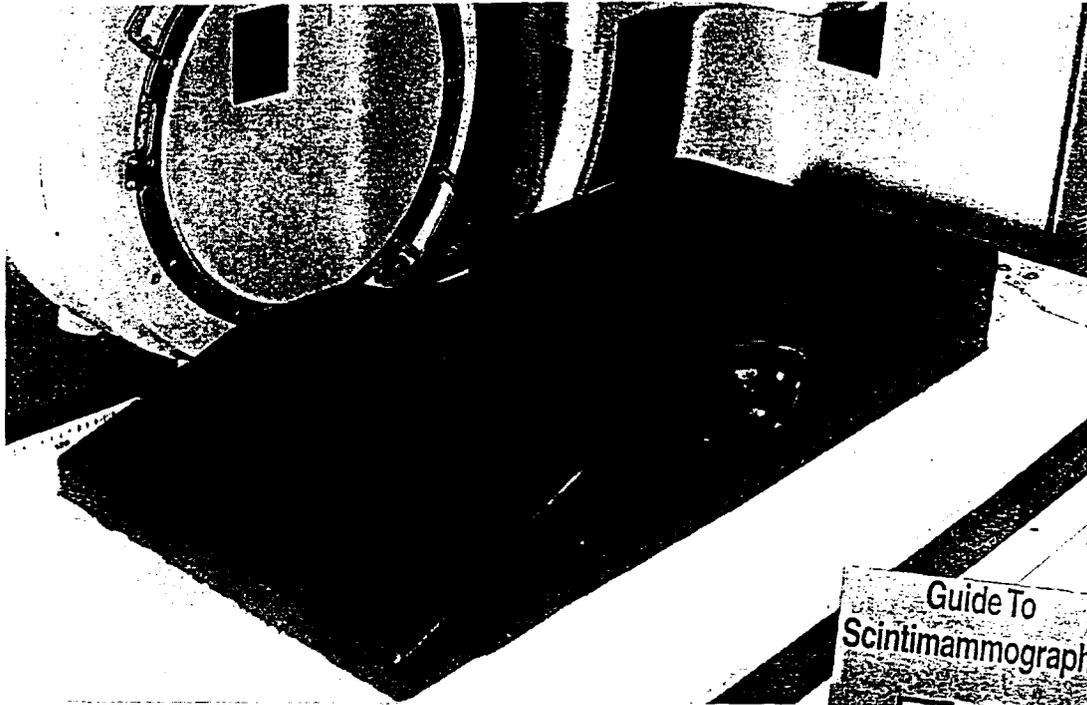
Name \_\_\_\_\_ Title \_\_\_\_\_  
Facility \_\_\_\_\_ Customer # \_\_\_\_\_  
Bill to Address: \_\_\_\_\_

Blue Nylon (Radiolucent)  
 T-Foam  Polyfoam  
Length \_\_\_\_\_ Width \_\_\_\_\_ Height \_\_\_\_\_  
Water Resistant Seams  Yes  No

*New!*

## SCINTIMAMMOGRAPHY PRONE BREAST CUSHION

*Now you can effortlessly and affordably perform scintimammography by using Nuclear Associates' Scintimammography Prone Breast Cushion and the FREE "Guide to Scintimammography."*



### The Scintimammography Prone Breast Cushion is an Innovative Product That:

- Provides optimal separation of the breast from the chest wall, making it easy to get **THE BEST RESULTS!**
- Allows lateral breast compression for larger imaging surfaces.
- Is free of attenuating materials, unlike expensive, bulky imaging tables.
- Allows you to image a full range of breast sizes—from an A cup to a double D.
- Is made of top-quality, medical-grade materials.
- Features an impermeable surface that is easy to clean.
- Can be used with any camera system; it's universal.
- Comes with an invaluable, **FREE "GUIDE TO SCINTIMAMMOGRAPHY"!**

*Was clinically proven in a study conducted by Departments of Nuclear Medicine, Surgery and Radiology, Hotel-Dieu de Montreal, University of Montreal, Canada, to evaluate the sensitivity and the specificity of <sup>99m</sup>Tc-sestamibi scintimammography in the detection of breast cancer and axillary lymph node involvement. (See next page for FREE reprint information.)*

### NUCLEAR ASSOCIATES



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## **SCINTIMAMMOGRAPHY TABLE OVERLAY**

- ***Simplifies patient positioning for Scintimammography imaging***
- ***Converts standard SPECT imaging tables to Scintimammography tables***
- ***Also available for standard flat bed planar imaging tables***
- ***Locking guide rails facilitate fast setup and removal of table overlay***

The Scintimammography Table Overlay is designed to improve the quality of prone breast imaging by providing a stable, more comfortable platform for your patient during a scintimammography procedure. Prone imaging allows the breast to be positioned free from the chest wall, which can greatly increase the target-to-background ratio. Your scanning table can now be fitted with the Scintimammography Table Overlay to provide the necessary indentations for prone imaging.

The Scintimammography Table Overlay is fabricated from a 1/2" thick polymer plastic material. The normal overall dimensions are 81" x 24" but will vary according to the size of your imaging table. Each table overlay is built to the specifications of your existing imaging table using locking guide rails. The system includes a 5/8" foam core heavy-duty vinyl pad. Please specify the model of your camera and table with your order.

<b>JRT-STO/S</b>	<b>Scintimammography Table Overlay for Spect Tables</b>	<b>\$ 1,330</b>
<b>JRT-STO/P</b>	<b>Scintimammography Table Overlay for Planar Tables</b>	<b>\$ 1,430</b>

### ***JRT Associates***

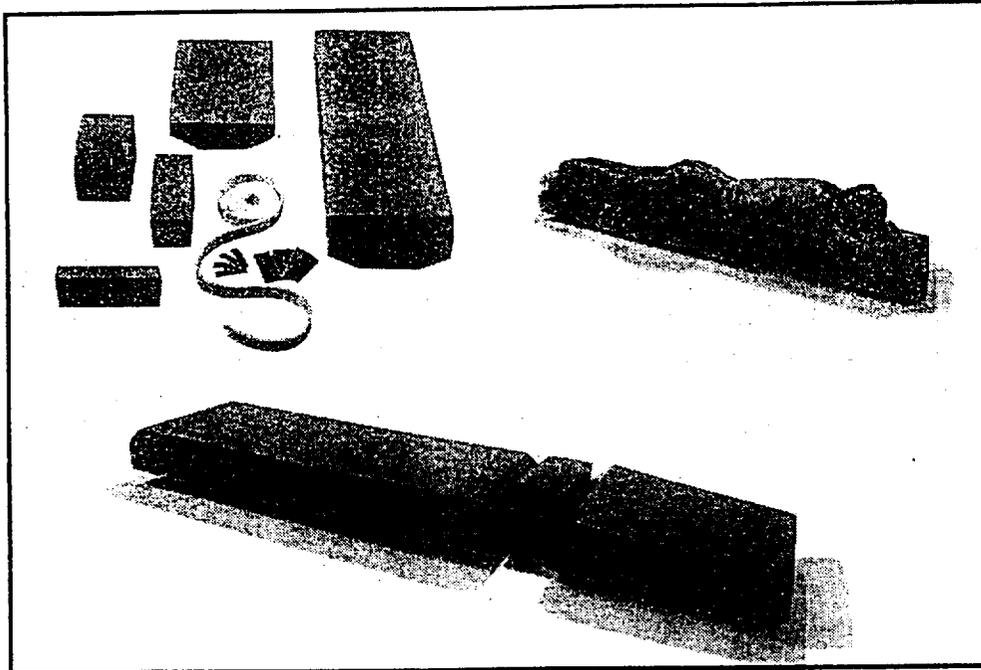
124 Saw Mill River Road

Elmsford, NY 10523

800-221-0111

FAX 914-592-3167

# Scinti Mammography Positioning Pads



Scinti  
Mammography  
Positioning  
Pads.

Part #PBI-3  
\$499<sup>00</sup>

- **Universal Imaging System Application** •
- **Comfortable, Anatomically Correct Positioning** •
- **Durable Seamless Foam Construction** •

*The specialized design of the positioning pads allow comfortable, anatomically correct, prone patient positioning on virtually any imaging system. The unique design of the pads makes right, left, or bilateral breast image acquisition easy.*

*Compatible with flat or concave imaging tables, the PBI-3 pad set comes with all the accessories needed to facilitate Scinti Mammography on your imaging system.*

**KIT INCLUDES:**

- 1 Upper Body Pad
- 2 Breast Compression Pads
- 1 Lower Body Pad
- 1 Ankle/Foot Rest Pad
- 1 Roll of Patient Safety Strap
- 4 Velcro Brand Mounting Strips

*Call today for complete details or a catalog of our entire product line.*



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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

NOV 10 1997

William H. Quirk  
Director, Regulatory Affairs  
KCI New Technologies Inc.  
3440 East Houston  
San Antonio, TX 78219

Re: K973915  
Inflatable Positioning Cushions  
Dated: October 9, 1997  
Received: October 14, 1997  
Regulatory class: II  
21 CFR 892.1710/Procode: 90 IZH

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) 594-4613. 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/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): \_\_\_\_\_

Device Name: Inflatable Positioning Cushions

Indications for Use:

The Inflatable Positioning Cushion device 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.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

*James G. Neenan*  
(Division Sign-Off)  
Division of Reproductive, Abdominal, ENT,  
and Radiological Devices  
510(k) Number K973915

Prescription Use   
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_

(Optional Format 1-2-96)