

***Premarket Notification [510(k)] Summary
as required by section 807.92(c)***

JUN - 6 1997

Date Summary was prepared:

March 4, 1997

Submitter's Name:

Victoreen, Inc.
6000 Cochran Road
Cleveland, Ohio 44139-3395

Contact Person:

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Director of Regulatory Affairs
and Quality Assurance
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Device Name:

Prone Breast Positioning Board, Model #37-018

Classification Name:

Medical Charged-Particle Radiation Therapy System

Predicate Device:

Med-Tec, Breast Board, Mt, 510(k) #935411

Device Description:

The Prone Breast Positioning Board is a linear accelerator couch-mounted platform which enables the breast to hang in a comfortable, gravity-dependent fashion for treatment with opposed tangential photon beams. Women with large or pendulous breasts, in whom supine treatment would result in an unacceptable dose inhomogeneity, are targeted as the

group who would benefit most from this device. Where dose to lung, heart or other normal tissue is also concerned, prone breast treatment offers advantages over supine treatment. The prone breast positioning device allows women to complete treatment expeditiously and minimize toxicity.

Intended Use:

To be used as a positioning device in patient set-up for primary breast irradiation.

Similarities to predicate device:

Both the Med-Tec Breast Board and the Prone Breast Positioning Board are used as positioning devices in patient set-up for primary breast irradiation.

Differences to predicate device:

The Med-Tec Breast Board is for supine positioning in treatment of the breast. The Prone Breast Positioning Board is for prone positioning in treatment of the breast. Listed below are the clinical and dosimetric advantages to prone breast positioning. (Please reference the attached article from The Official Journal, entitled "Prone Position Breast Irradiation," by Thomas E. Merchant, D.O., and Beryl McCormick, M.D.)

Clinical advantages:

1. Women with large or pendulous breast may be treated with ease:
 - facilitates breast conserving therapy for large breasted women
 - improves reproducibility of treatment for large breasted women
2. The lung and heart may be avoided through this positioning technique:
 - important for women with pre-existing cardiac and pulmonary conditions
 - reduces the chance of long-term effects on heart and lungs
3. Significantly reduces skin reaction through improved dose homogeneity:
 - treatment breaks are less likely due to improved skin tolerance

-allows treatment to be given in a continuous course-oncologically superior

-may facilitate simultaneous administration of chemotherapy in some women

-may allow patients with connective tissue disorder to receive treatment

4. Prone positioning simplifies breast boosts by making photon treatment possible:

-avoids the need for electron capability when treating breast patients

-skin-sparing boost treatment (photons) decreases skin reactions

Dosimetric advantages:

1. The amount of internal scatter is markedly reduced:

-the volume of chest wall irradiated can be reduced by this technique

2. Radiation scatter to the contralateral (opposite) breast can be minimized:

-the opposite breast can be moved away from the field edge

3. Beam attenuators (wedges) are not required to improve homogeneity:

-the number of accelerator monitor units required for treatment is less

-internal scatter and scatter to the opposite breast are further minimized

Non-clinical Performance Data:

Two sample treatment plans (exhibits F and G) labeled "Jones, Pearl" are attached. The treatment plan marked with the 0.75, 0.75 scale is a prone treatment plan and supine on the same page for the same patient. The one with the 0.5, 0.5 scale is a conventional (parallel opposed) supine treatment plan. The sample treatment plans clearly show that in the supine treatment the dose to the chest wall is 90% of the max dose, whereas in the supine plan it is 110% of the max dose. Also the supine plan has hot spots near both beam entrance points of 123% of max dose, while the prone position provides a very uniform distribution with a uniform gradient through the breast. It is important to note that in

breast conserving treatment, radiation therapy is treating the intact breast and a uniform, homogeneous dose distribution is desired if one is to achieve local control without complications such as skin reactions.

Cinical Study/Test Data:

Please reference: Exhibit "H" The article from The Official Journal, entitled "Prone Position Breast Irradiation," by Thomas E. Merchant, D.O., and Beryl McCormick, M.D.

 Exhibit "I" The article entitled "Dose to Lung in Primary Breast Irradiation"

Safety and Effectiveness Conclusion:

The conclusions drawn from the enclosed medical physics test data (see sample treatment plan/180 dose distributions in "F" and "G" Exhibits), and the supportive clinical articles (Exhibits "H" and "I") demonstrate that the Prone Breast Board (Model 37-018) presents no new issues relating to safety and effectiveness and is substantially equivalent to the legally marketed predicate device listed on page one of this document.



JUN - 6 1997

Food and Drug Administration
3200 Corporate Boulevard
Rockville MD 20850Linda S. Nash
Director of Regulatory Affairs
and Quality Assurance
Victoreen, Inc.
6000 Cochran Road
Cleveland, OH 44139-3395Re: K971382
Prone Breast Positioning Board, Model #37-018
Dated: March 4, 1997
Received: April 14, 1997
Regulatory class: II
21 CFR 892.5050/Procode: 90 IYE

Dear Mr. Nash:

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 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.

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) 594-4591 for Radiology devices, or 594-4613 for Ear, Nose and Throat devices. 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:

Device Name: Prone Breast Positioning Board, model number 37-018

Indications for Use:

The Prone Breast Positioning Board, model number 37-018 is to be used as a positioning device in patient set-up for primary breast irradiation.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Segman
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K971382

Prescription Use

or

Over-The-Counter Use