K100691

510(k) Summary:

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Corporate Office

5154 Enterprise Blvd., Toledo, Ohio 43612

Date of Application: 2/26/10

Applicant: Bionix Development Corporation
5154 Enterprise Blvd.
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Device Name: Omni V SBRT Positioning System

Common Name: Whole Body Stereotactic Immobilizer

Classification Name: Accessory to Accelerator, Linear, Medical (Per CFR section 892.5050)

Intended Use:

The Omni V SBRT Positioning System from Bionix Development Corporation is intended to be used for stereotactic localization and positioning of patients undergoing or receiving a course of external beam radiation therapy for the treatment of cancer and other diseases.

Substantial Equivalence Device(s):

This product is similar in design and function to existing patient positioning devices currently in use as accessories to radiation therapy systems. One such device is the BodyFix, manufactured and legally marketed by Medical Intelligence, Germany. This device is listed under regulation number 892.5050, Accessory, Accelerator, Linear, Medical, and is classified as a Class II device. This device has been cleared by the FDA under K013391.

The BodyFix immobilization device is used to immobilize a patient in a fashion that allows stereotactic localization and verification of position. The BodyFix uses a reference system which is external to the patient's body. Using this reference system, the coordinates of a target can be reproducibly localized during a course of radiation therapy. The BodyFix uses a vacuum cushion posteriorly to position the patient, then achieves immobilization with a vacuum sheet anteriorly that evacuates to conform tightly to the patient's body.

Another such device is the BodyLoc system manufactured and legally marketed by Medical Instrumentation & Diagnostics Corporation (MIDCO), San Diego, CA. This device is listed under regulation number 892.5050, Accessory, Accelerator, Linear, Medical, and is classified as a Class II device. This device has been cleared by the FDA under K991336.

The MIDCO BodyLoc system is designed to immobilize and position patients for a course of stereotactic radiation therapy. The BodyLoc system achieves patient immobilization by the use of a vacuum molded cushion system for posterior areas, and low-melt thermoplastic (anteriorly) to cover large body surfaces in the anterior plane. The method of combined anterior and posterior form fitting custom molded immobilization materials that cover wide surface areas improves immobilization and repositioning, as well as minimizes diaphragmatic movements.

The BodyLoc is a body stereotactic localizer system which utilizes a coordinate reference system that can be used to reproducibly localize targets during diagnostic and treatment procedures. Patients immobilized in the frame are imaged with CT and/or MR imaging to localize the target area. The BodyLoc uses stereotactic localization fiducials positioned in the sides and base of the device, as well as a moveable arc localizer for target alignment. Targets are calculated and the patient, again immobilized in the frame, is positioned on the LINAC couch according to calculated stereotactic targets.

Device Description:

Overview.

This pre-market notification is being submitted in good faith in an effort to satisfy the requirements of the FDAMA guidelines. Additionally, the FDA does not have any voluntary standards for this device and no standards have been applied.

The Bionix Omni V stereotactic body radiation therapy (SBRT) positioning system is intended to be used for stereotactic localization and positioning of patients undergoing or receiving a course of external beam radiation therapy for the treatment of cancer and other diseases. This device has been most likely classified as Class II by the FDA Panel on Radiology, falling under CFR 892.5050.

The Bionix Omni V SBRT system has been designed using the design control procedures of the Bionix Quality System in compliance with the Good Manufacturing Practice

(GMP) Quality System Regulations of the FDA/CDRH. This pre-market notification will draw information from the Design History File for this device and format it for efficient review.

Background and Principles of Operation.

The Bionix Omni V stereotactic body radiation therapy positioning system is intended to be used for stereotactic localization and positioning of patients undergoing or receiving a course of external beam radiation therapy for the treatment of cancer and other diseases.

The Omni V SBRT positioning system from Bionix Development Corporation has several component parts that are designed to work together to provide an easy to use means of reproducibly positioning a patient undergoing external beam stereotactic radiation therapy.

The Omni V system starts with the thermoformed base. The base is thermoformed from an acrylic/PVC alloy material so that the resulting contoured shell is light-weight and thin-walled, providing low attenuation for unobstructed passage of the radiation therapy beam. This construction forms a light-weight, radiolucent, rigidly stable base support for the system. The base has molded-in attachment points for the other components of the system: the body support vacuum cushion, the upper arm support, and the thigh and foot bolster. Integrated rails that run the length of either side of the base provide attachment points for the breath-suppression and fiducial arches. The rails and attachment points are indexed to allow for reproducible positioning of the patient.

The Omni V thermoformed acrylic/PVC alloy shell displays minimal attenuation of the radiotherapy beam. This is due primarily to the fact that the thermoformed shell is relatively thin, with an open, air filled core that is radiolucent. The resulting structure provides strength and rigidity, and is ideal for producing a device that reproducibly positions patients and yet does not interfere with the administration of therapeutic radiation. Patient positioning devices with this type of structure are common in radiation therapy.

The Omni V base has attachment holes that allow it to mate with an attachment bar that can lock onto the treatment couch tabletop. This allows the Omni V SBRT system to be repeatedly located in the same position on the treatment couch tabletop for each therapy session.

The Omni V base has specific topographic features—central thermoformed opening and contoured ridges—that allow the use of a body support vacuum cushion as part of the patient immobilization process. These topographic features act to locate the body support vacuum cushion and lock it in place. Vacuum cushions contain expanded polystyrene beads in an airtight vinyl bag, with a valve for attachment to a vacuum pump. In practice, the patient is positioned atop the bag which is then evacuated using the vacuum pump. As the bag is evacuated, the polystyrene beads form a rigid cushion that accurately conforms to the contours of the patient's anatomy, and also to the contours of the

thermoformed opening in the base. The latter allows the vacuum cushion to locate reproducibly onto the Omni V base, while the patient can be reproducibly located into the impression formed into the vacuum cushion.

The body support vacuum cushion for the Omni V SBRT positioning system differs from common vacuum cushions in significant ways. First, it is longer than average, allowing full support of the body from legs to head. This is needed to provide immobilization for the entire body, not just a small portion. Second, the Omni V body support vacuum cushions have multiple chambers, rather than one large, single-chambered bag. This novel approach allows separate body segments to be molded individually, giving greater control of the molding procedure to the radiation therapists and improving the body fixation process.

Patients undergoing stereotactic radiation therapy have to lie in one position for a lengthy time period. The Omni V SBRT system upper arm support takes the pressure off the arms, allowing the patient to remain comfortable and motionless during the treatment session. The Omni V upper arm support has two parts, a wing board that provides support for the patient's upper arms and assists positioning and molding of the upper body support vacuum cushion, and an arm rest. Both the wing board and the arm rest interlock with the Omni V base using the molded-in attachment points in the base. To account for patient size differences and comfort, the arm rest is adjustable and indexed for reproducibility.

To further position and immobilize the lower extremities, the Omni V features a thigh and foot bolster. Similar to the upper arm support, this component positions and holds the thighs and feet motionless during the treatment session. The thigh and foot bolster locks into the device base using the attachment points molded into the base. In use, the thigh and foot bolster will abut the patient support cushion to provide total body support for the patient. Again, like other components in this system, the thigh and foot bolster is adjustable and indexed for reproducibility.

Many internal organs, notably the lungs and prostate, show significant positional change with the act of respiration. Studies have shown that these positional changes can range from millimeters to several centimeters with the prostate. This can lead to treatment field errors, and/or the need to expand the treatment field to include the entire region of organ movement. To improve treatment accuracy in stereotactic radiation therapy, it is desirable to reduce organ movement associated with respiration by limiting the respiratory effort. In the Omni V SBRT system, this is done by suppressing chest wall movement during respiration by applying pressure to the chest via the breath-suppression arch.

The breath-suppression arch attaches to the rails that run the length of either side of the Omni V base. The function of the breath-suppression arch is to apply compressive pressure to the chest to reduce chest-wall movement with breathing. The arch is designed to slide along the rails, allowing the therapist to locate the arch over the patient's chest, and then is locked into position on the rails, providing reproducible, indexed positioning.

A chest compression plate is lowered from the apex of the breath-suppression arch contacting the chest wall; this plate is lowered until the patient's chest wall movement is minimized without compromising the patient's respiratory ability.
The Omni V SBRT system also includes a fiducial arch that slides along and fixes onto the rails of the thermoformed base in an indexed fashion, similar to the breath-suppression arch. The fiducial arch has markings that are visible on x-ray and MRI, providing a reference system that is external to the body. Using the fiducial arch, the coordinates of a target can be accurately and reproducibly localized during both the set-up/simulation procedures and through a course of radiation therapy.

In clinical practice, the Bionix Omni V stereotactic body radiation therapy positioning system base is secured to the therapy couch tabletop by attachment to a lock-down bar. The patient is positioned on the Omni V, using the components of the Omni V SBRT system—body support vacuum cushion, upper arm support, and thigh and foot bolster—to immobilize the patient in a comfortable, indexed, and reproducible position. The breath-suppression arch is moved and lowered to constrain chest wall movement, and the fiducial arch is positioned to provide an external reference system to ensure treatment accuracy. Once positioned, the patient can then undergo simulation for treatment planning purposes, or begin his/her course of external beam radiation therapy as prescribed.

Comparison to Predicate Device:

This Omni V from Bionix Development Corporation is similar in design and function to existing patient positioning devices currently in use as accessories to radiation therapy systems. One such device is the BodyFix, manufactured and legally marketed by Medical Intelligence, Germany. The BodyFix immobilization device is used to immobilize a patient in a fashion that allows stereotactic localization and verification of position.

The principal parts of the BodyFix system are the base-plate, the vacuum cushion, fixation sheet, and the target positioner and localizer. The BodyFix base-plate is constructed of a carbon fiber/foam composite material for enhanced radiolucency. Such structures are commonplace in radiation therapy positioning products to provide rigidity and support while at the same time minimizing attenuation of the radiation therapy beam.

The base of the Omni V SBRT system is thermoformed from an acrylic/PVC alloy material. Such materials are commonly used in radiation therapy positioning devices to provide radiolucency and rigidity. The resulting base-plate for the Omni V is lightweight and thin-walled, providing low attenuation for unobstructed passage of the radiation therapy beam.

The BodyFix uses a vacuum cushion posteriorly to position the patient. Vacuum cushions contain expanded polystyrene beads in an airtight vinyl bag, with a valve for attachment to a vacuum pump. In practice, the patient is positioned on the bag which is then evacuated using the vacuum pump. As the bag is evacuated, the polystyrene beads form a rigid cushion that accurately conforms to the contours of the patient.

The Omni V also uses a patient support vacuum cushion, but it differs from common vacuum cushions in significant ways. First, it is longer than average, allowing full support of the body from legs to head. This is needed to provide immobilization for the entire body, not just a small portion. Second, the Omni V body support vacuum cushions have multiple chambers, rather than one large, single-chambered bag. This novel approach allows separate body segments to be molded individually, giving greater control of the molding procedure to the radiation therapists and improving the body fixation process.

Final patient immobilization in the BodyFix is achieved with a vacuum sheet anteriorly that evacuates to conform tightly to the patient's body. This limits both patient movement as well as chest wall excursion during respiration.

For the Bionix Omni V, full patient immobilization is achieved by combining the body support vacuum cushion positioning with that of the upper arm support and the thigh and foot bolster, all of which index to the thermoformed base-plate. Chest excursion during respiration is minimized through use of the breath-suppression arch.

The BodyFix uses a target positioner and localizer that are indexed to the base-plate to produce a reference system which is external to the patient's body. Using this stereotactic system, the coordinates of a target can be reproducibly localized during a course of radiation therapy.

In similar fashion, the fiducial arch of the Bionix Omni V SBRT system provides an external reference system that may be used to reproducibly localize the patient during a course of radiation therapy.

Another such device is the BodyLoc system manufactured and legally marketed by Medical Instrumentation & Diagnostics Corporation (MIDCO), San Diego, CA. The MIDCO BodyLoc system is designed to immobilize and position patients for a course of stereotactic radiation therapy.

The main component parts of the MIDCO BodyLoc system are the base-plate, the posterior vacuum cushion, the anterior low-melt thermoplastic body mask, the stereotactic localization fiducials positioned in the sides and base of the device, and a moveable arc localizer for target alignment.

The MIDCO BodyLoc base-plate is constructed from acrylic sheet material. While commonly used in radiation therapy positioning devices due to its low cost and machine-ability, acrylic does not have the lower radiation attenuation values seen with thermoformed structures such as are used in the Bionix Omni V. The Omni V acrylic/PVC alloy thermoformed base is light-weight and thin walled yielding superior radiolucency while maintaining rigidity for patient support.

The BodyLoc system achieves patient immobilization by the use of a vacuum molded cushion system for posterior areas, and low-melt thermoplastic (anteriorly) to cover large body surfaces in the anterior plane. The method of combined anterior and posterior form fitting custom molded immobilization materials that cover wide surface areas improves immobilization and repositioning, as well as minimizes diaphragmatic movements.

The Bionix Omni V uses a unique, multi-chambered body support vacuum cushion to position the patient. This novel approach allows separate body segments to be molded individually, giving greater control and ease to the therapists and improving the body fixation process.

Low-melt thermoplastic is not used in the Omni V. Instead, full patient immobilization is achieved by combining the body support vacuum cushion positioning with that of the upper arm support and the thigh and foot bolster, all of which index to the thermoformed base. Chest excursion during respiration is minimized through use of the breath-suppression arch.

The BodyLoc has a body stereotactic localizer system which utilizes a coordinate reference system that can be used to reproducibly localize targets during diagnostic and treatment procedures. The BodyLoc uses stereotactic localization fiducials positioned in the sides and base of the device, as well as a moveable arc localizer for target alignment. Targets are calculated and the patient, again immobilized in the frame, is positioned on the LINAC couch according to calculated stereotactic targets.

In similar fashion, the fiducial arch of the Bionix Omni V SBRT system provides an external reference system that may be used to reproducibly localize the patient during a course of radiation therapy.

Conclusion:

The similarity of design, features, radiolucency, and function indicate that the Omni V stereotactic body radiation therapy positioning system from Bionix Development Corporation will perform as well as the legally marketed BodyFix system from Medical Intelligence and the legally marketed BodyLoc system from MIDCO for the intended use of stereotactic localization and positioning of patients undergoing or receiving a course of external beam radiation therapy for the treatment of cancer and other diseases.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

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MAY 11 2010

Re: K100691
Trade/Device Name: Omni V SBRT Positioning System
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: February 26, 2010
Received: March 10, 2010

Dear Dr. Huttner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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 class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 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 Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donald J. St.Pierre
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K100691

Device Name: Omni V SBRT Positioning System

Indications for Use:

The Omni V SBRT Positioning System developed and manufactured by Bionix Development Corp., Toledo, Ohio, is intended to be used for stereotactic localization and positioning of patients undergoing or receiving a course of external beam radiation therapy for the treatment of cancer and other diseases.

It is intended to be used by or under the direction of a licensed physician.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K100691

Page 1 of 1