K100264

APR - 9 2010

510(k) Summary

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Date of Application: 11-20-09

Applicant:
Bionix Development Corporation
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Contact:
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Device Name: T-Form Extremities Immobilizer

Common Name: Extremity Immobilizer

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

Intended Use:

The T-Form Extremities Immobilizer from Bionix Development Corporation is designed to be used for the positioning and re-positioning of patients for receiving external beam radiation therapy.

Substantial Equivalence Device:

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 Multifix, manufactured and legally marketed by Civco Medical Solutions of Orange City, Iowa. 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 K060737.

The Multifix is a positioning device that allows arms and legs to be fixed in straight or bent positions for external beam radiation therapy. The Multifix has a base-plate that may be made of acrylic or carbon fiber. The base-plate has four sets of holes that are

indexed to ensure a reproducible setup of the treated extremity. Once positioned, the extremity is held in place by low-melt thermoplastic sheets that are molded to the extremity and secured by locking into one of the indexing holes on the base-plate.

Another such device is the HipFix, manufactured and legally marketed by Civco Medical Solutions of Orange City, Iowa. 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 with K950866.

The HipFix hip and pelvis immobilization system is used to position and immobilize the hips and lower extremities during a course of radiation therapy. The HipFix immobilization system utilizes a single sheet of thermoplastic over the abdomen and pelvis region to provide immobilization and enhance fixed fiducial targeting. The HipFix base-plate features a cutout treatment window, and the base-plate can be indexed to the couch top. A vacuum cushion can be integrated to the HipFix for added comfort and repositioning accuracy.

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 T-Form Extremity Immobilizer is intended to be used for the positioning and re-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 T-Form Extremity Immobilizer 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 T-Form Extremity Immobilizer is intended to be used for the positioning and re-positioning of patients undergoing or receiving a course of external beam radiation therapy for the treatment of cancer and other diseases.

The T-Form Extremity Immobilizer from Bionix Development Corp. consists of a thermoformed patient support device with attachment areas for accessories. The T-Form Extremity Immobilizer is thermoformed from an ABS plastic material so that the resulting contoured shell is lightweight and thin-walled, providing low attenuation for

unobstructed passage of the radiation therapy beam. The T-Form Extremity Immobilizer is specifically designed for immobilization of the upper and lower extremities.

The T-Form Extremity Immobilizer has a generally rectangular shape, with pre-formed areas that allows.the device to be securely attached to the treatment couch tabletop. Specifically, there are pre-formed depressions with threaded holes that allow the T-Form Extremity Immobilizer to screw onto an attachment bar that can lock onto the treatment couch tabletop. These pre-formed areas can be found on both the top and side of the device, allowing the T-Form Extremity Immobilizer to be used in either a longitudinal or transverse orientation to allow greater flexibility in patient positioning. This allows the T-Form Extremity Immobilizer to be repeatedly located in the same position on the treatment couch tabletop for each therapy session.

The T-Form Extremity Immobilizer has a central thermoformed depression to allow the use of optional vacuum cushions as part of the patient immobilization process. Vacuum cushions contain expanded polystyrene beads in an airtight vinyl bag, with a valve for attachment to a vacuum pump. In practice, the patient's extremity 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's extremity, and also to the sides of the thermoformed depression. The latter allows the vacuum cushion to locate reproducibly onto the board, while the patient's extremity can be reproducibly located into the pocket formed into the vacuum cushion.

Attachment points for standard low-melt thermoplastic (used to restrain patients undergoing radiation therapy) are provided for use in immobilizing the patient's extremities. A simple mechanical interlocking system allows the attachment of the low-melt thermoplastic to the T-Form Extremity Immobilizer. Low-melt thermoplastic has the property of becoming soft and pliable when warm so that it can be stretched over and molded to the contoured shape of an object, in this case the patient. As it cools, it becomes rigid, and retains the object's shape. For the T-Form Extremity Immobilizer two non-adherent plastic handles are used to hold the low-melt thermoplastic. Simple screw-tightened clamps mounted on the surface of the T-Form Extremity Immobilizer are used to secure the non-adherent plastic handles to the board. The low-melt thermoplastic sheet is stretched over the patient's extremity in its pliable form; once molded to the patient's anatomy, the customized low-melt thermoplastic sheet can be placed over the patient and "locked down" to the T-Form Extremity Immobilizer to ensure proper positioning for every therapy session.

The Bionix T-Form Extremity Immobilizer has a thermoformed ABS shell that displays minimal attenuation of the radiotherapy beam. This is due primarily to the fact that the thermoformed shell is relatively thin. The device has 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. They come in many varieties and are manufactured by several companies; examples including Civco Medical Solutions.

In clinical practice, the Bionix T-Form Extremity Immobilizer is secured to the therapy couch tabletop by attachment to a lock-down bar. The patient's extremity is positioned on the T-Form Extremity Immobilizer as desired, either directly onto the board or with the use of a vacuum cushion that has been evacuated to conform to the patient's anatomy. Low-melt thermoplastic is heated, and then draped in its warm, pliable state over the patient's extremity, and then secured to the T-Form Extremity Immobilizer using the screw-down clamps. When it cools, the low-melt thermoplastic becomes rigid and retains the shape of the patient's extremity, allowing it to be positioned and re-positioned securely during the radiation therapy regimen. Radiation therapy is then administered in the usual fashion.

Comparison to Predicate Device:

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 Multifix, manufactured and legally marketed by Civco Medical Solutions of Orange City, Iowa. The Multifix immobilization system is used to position and immobilize the upper and lower extremities during a course of radiation therapy. Another such device is the HipFix, also manufactured and legally marketed by Civco Medical Solutions of Orange City, Iowa. The HipFix hip and pelvis immobilization system is used to position and immobilize the hips and lower extremities during a course of radiation therapy.

The Multifix has a base-plate that may be made of acrylic sheet, or preferably, from 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-plate has four sets of indexed holes allowing the extremity to be reproducibly positioned in either a straight or bent position. The base-plate is also provided with attachments to a lock-down bar so that the device can be indexed to the treatment couch tabletop.

The HipFix base-plate is constructed of a carbon fiber/foam composite material for enhanced radiolucency. The HipFix base-plate also features a cutout treatment window, again to enhance radiolucency in the treatment field. The HipFix base-plate is provided with attachments to a lock-down bar so that the device can be indexed to the treatment couch tabletop.

In the T-Form Extremity Immobilizer by Bionix Development Corporation, a thermoformed ABS plastic shell is used instead of a carbon fiber/foam composite material to provide radiolucency and rigidity. The resulting device is lightweight and thin-walled, providing low attenuation for unobstructed passage of the radiation therapy beam. Using a thermoformed plastic design makes a cut-out treatment window unnecessary for the Bionix T-Form Extremity Immobilizer.

In the Multifix device, several small sheets of low-melt thermoplastic are molded to the extremity and secured by locking into one of the indexing holes on the base-plate.

The low-melt thermoplastic provides immobilization and isocentric positioning of the target limb.

The HipFix immobilization system utilizes a single sheet of low-melt thermoplastic over the abdomen and pelvis region to provide immobilization and enhance fixed fiducial targeting. A vacuum cushion can be integrated to the HipFix for added comfort and repositioning accuracy.

In similar fashion, the Bionix T-Form Extremity Immobilizer uses a sheet of low-melt thermoplastic to conform to the patient's extremity to provide immobilization and ensure proper positioning for every therapy session. The T-Form Extremity Immobilizer also has a thermoformed depression to facilitate the positioning of optional vacuum cushions as part of the patient immobilization process.

Conclusion:

The similarity of design, features, radiolucency, and function indicate that the T-Form Extremity Immobilizer from Bionix Development Corporation will perform as well as the legally marketed Multifix and HipFix immobilization devices from Civco Medical Solutions for the intended use of positioning and re-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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Re: K100264
Trade/Device Name: T-Form Extremities Immobilizer
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: January 20, 2010
Received: January 28, 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): (Not known) K100264

Device Name: T-Form Extremities Immobilizer

Indications for Use:

The Bionix T-Form Extremities Immobilizer patient positioning system, developed and manufactured by Bionix Development Corp., Toledo, Ohio, is intended to be used for the positioning and re-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____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, ~~Office of Device Evaluation (ODE)~~ ODUD

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

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