

K050372

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Contact Person: Wendel Dean Renner, President of Math Resolutions, LLC
Date: March 17, 2005

510(k) Summary

VisiTrak is a radiation therapy localization software system that assist in aiming the radiation beam. This software uses functions from System 2100, a Radiological Image Display System, 510(k) K993530, and Dosimetry Check, a treatment plan delivery testing system, 510(k) K010225.

The trade name is VisiTrak. A common name is imaged guided radiation therapy. Regulatory Class is II.

A predicate device is Acculoc from Northwest Medical Physics Equipment, 21031 67th Ave. West, Lynnwood, WA 98036, 510(k) K970464. VisiTrak and Acculoc both mathematically solves for the x,y,z coordinates of the couch so that the projected image of a designated marker and the radiographic image of the same marker coincide on orthogonal views.

The following functions are included in VisiTrak:

- (1) Means to download a treatment plan from a treatment planning system, to include a stackable image set (such as the CT scans used to generate the plan), beam geometry, and optional regions of interest outlines. [This function from Dosimetry Check]
- (2) Means to define and trace a marker that is visible in the stackable image set. [This function from System 2100]
- (3) Means to draw the markers on two dimensional plane images and three dimensional perspective room views.
- (4) Means to read in radiographic images made of the patient in the treatment position on the gantry mounted treatment machine.
- (5) Means to define the geometry for each radiographic image, i.e., in the treatment machine coordinates.

- (6) Means to project the defined markers onto the radiographic images.
- (7) Means to manually select couch coordinates to match up the images of the markers on the radiographs with the projected marker images.
- (8) Means to trace the images of the markers on the radiographs.
- (9) Means to solve for the best estimate of the couch coordinates that will align the projected and traced marker images.
- (10) Means to display the couch coordinates for each treatment beam using the couch position found in (7) or (9) above.

The intended use of the device is by radiation oncologist and their therapy technicians and physicist to solve for the couch coordinates for each radiation therapy treatment of a radiation therapy patient to properly align the isocenter of the treatment machine with the isocenter location within the planning image set (typically CT) that was planned on a radiation therapy treatment planning system. Some internal or external marker must be visible on both radiographs of the patient taken at the time of treatment and the sectional images used for the treatment plan.

Document Approved by: Wendel Dean Renner
Title: President of Math Resolutions, LLC

Signature:

Date: March 17, 2005



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Wendel Dean Renner
President
Math Resolutions, LLC
5975 Gales Lane
COLUMBIA MD 21045

Re: K050372
Trade/Device Name: VisiTrak
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle
radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: February 11, 2005
Received: February 14, 2005

Dear Mr. Renner:

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 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 898. 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 Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). 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) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number: **K050372**

Device Name: VisiTrak

Indications for Use:

This product is to be used by radiation therapy oncologist or staff under their direction to locate the position relative to the patient of the isocenter of a treatment beam on a gantry mounted radiation therapy treatment machine. Some internal or external marker must be visible on both a radiograph of the patient taken at the time of treatment and the images used for the treatment plan in order to use this software to align the marker image on the radiograph with the plan to find the proper patient support system coordinates. Only a translation along the couch lateral, longitudinal, and height directions are considered and solved for. Possible rotations or repositioning of the patient are not considered.

Document Approved by: Wendel Dean Renner
Title: President, Math Resolutions, LLC

Signature: *Wendel Dean Renner*

Date: *Feb, 2005*

Prescription Use

Nancy C. Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K050372