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510(k) Summary of Safety and Effectiveness
I-Beam Patient Positioning System

Submitter Name:	Computerized Medical Systems, Inc.
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Contact Person:	Michael A. Parsons - Director - Quality Assurance and Regulatory Affairs or Kathryn Stinson – Regulatory Affairs Associate
Date Summary Prepared:	July 2003
Device Trade Name:	I-Beam
Device Common Name:	Patient Positioning System
Device Classification:	System, Simulator, Radiation Therapy per 21CFR892.5840
Substantial Equivalence:	NOMOS BAT Ultrasound Localization and Positioning System (K981424) Brainlab ExacTrac 2.0 Ultrasound Localization System (K003285)

Device Description: The I-Beam Patient Positioning System provides a method for a hospital/clinic to accurately position a patient prior to delivery of external beam radiation therapy each day such that the patient tumor volume on the day of therapy coincides with the tumor volume from the treatment plan. Patient positioning may be necessary because of day-to-day movement of the soft tissue target within the patient. Closer alignment assures proper tumor coverage and a minimum of dose to healthy tissue and structures surrounding the target.

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I-Beam achieves this alignment by having a camera provide a signal to I-Beam. The camera is attached to an ultrasound transducer body by use of a custom "clamshell" in an orientation that points the camera in a direction 180 degrees from the plane of the transducer output. As the transducer ultrasound system (not part of I-Beam) images the patient target, the camera is looking up at a targeting grid located on the shadow tray of the linear accelerator. Using pattern recognition techniques, the I-Beam system is able to determine the position of the isocenter of the target volume relative to the isocenter of the linear accelerator. The user then superimposes the ultrasound tumor volume data obtained from this scan on that from the original treatment plan data input to I-Beam earlier. This treatment plan is based on a CT study set, and the user aligns the two tumor volumes by "moving" one relative to the other. I-Beam senses this relative movement of the ultrasound tumor volume to that from the treatment plan and converts that into a three axis "translation" figure which gives the operator the amount and direction the patient must be moved in each axis to achieve alignment with the treatment plan and thus the linear accelerator. Correct re-positioning of the patient is verified by performing a second ultrasound scan of the patient and overlaying that with the original CT-based treatment plan tumor volume information. The translation figures will advise the user of any remaining misalignment should there have been a misinterpretation of the translation date and/or patient positioning.

Device Intended Use: I-Beam is a self-contained mobile patient positioning system that uses real time ultrasound images of patient target organs or tumors while the patient is positioned on the couch of the linear accelerator to confirm the location of these patient target organs or tumors prior to delivery of external beam radiation therapy.

Summary of Technological Characteristics Compared to Predicate Devices: The predicate devices can both use ultrasound imaging of the target volume on the day of treatment to determine the amount of target movement relative to the original treatment plan data and provide the user feedback on correct patient positioning for that day's therapy.

ExacTrac outputs the automatic couch movement in three dimensions necessary to re-position the tumor volume. BAT has an interface to the treatment couch to determine when the necessary patient movement to achieve alignment has been performed. I-Beam outputs the direction and amount of patient movement to achieve alignment onto the system display and this is verified during a second patient scan after repositioning.

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Summary of Clinical Testing: Actual testing in a clinic was not performed as part of the development of this feature. Clinical testing is not required to demonstrate substantial equivalence or safety and effectiveness of the device.

Summary of Non-Clinical Testing: Both verification and validation test cases were written and executed to assure the system is correctly measuring patient tumor volume shift as well as outputting correct patient "translation" to achieve alignment of planned versus actual patient tumor volume. This testing also verified correct operation of the optical alignment target and the camera and the ability of I-Beam to convert this information into clinically correct patient repositioning information.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 2 2003

Ms. Kathryn Stinson
Regulatory Affairs Associate
Computerized Medical Systems, Inc.
1145 Corporate Lake Drive, Suite 100
ST. LOUIS MO 63132

Re: K032100
Trade/Device Name: I-Beam Patient Positioning System
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: 90 IYE
Dated: July 7, 2003
Received: July 8, 2003

Dear Ms. Stinson:

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 (PMA), it may be subject to 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 the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

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" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

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

Enclosure

Statement of Indication for Use

510(k) Number: K032100

Device Name: I-Beam Patient Positioning System

Indication for use: I-Beam is a self-contained mobile patient positioning system that uses real time ultrasound images of patient target organs or tumors while the patient is positioned on the couch of the linear accelerator to confirm the location of these patient target organs or tumors prior to delivery of external beam radiation therapy.

Concurrence of the Center for Devices and Radiological Health,
Office of Device Evaluation (ODE)

Prescription Use ✓ OR per 21 CFR 801.109 Over the Counter Use _____

David A. Ingram

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K032100