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Medical Instrumentation & Diagnostic Corporation (MIDCO)
FDA Establishment Reg. #17211849
CASS System Reg. # K894263A

cass

510(k) Summary

As required by section 807.92(c)

cass Linac Radiosurgery Hardware Couchmount Stereotactic Frame Support System

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510(k) Product Information for:

cass Linac Radiosurgery Hardware
Couchmount Stereotactic Frame Support System

Trade name: cass Photon Knife

Common name: Radiosurgery Couchmount System

Classification name: X-ray Radiation Therapy System (accessory)
(per 21 CFR Section 892.550)

Device Class: Class II (90)IYE

FDA Document numbers of prior related submissions:

K894263/A K911750/A K9217401/B

Information on devices to which substantial equivalence is claimed:

a. F.L. Fischer---Liebinger LP
14540 Beltwood Parkway East
Dallas, Texas 75244
Product Name: STP Stereotaxic Convergent Beam Irradiation System
Document Control Number: K892425

b. Radionics
76 Cambridge Street
Burlington, Massachusetts 01803-0738
Product Name: X-Knife Radiosurgery System
Document Control Number: K912630

Device Description:
cass Linac Radiosurgery Hardware Couchmount Stereotactic Frame Support System

MIDCO has recently developed a quality Couchmount System (Patient Head Support System) for use in radiosurgery. This couchmount system complements the cass collimator set and enables MIDCO to provide its customers with a full set of instrumentation necessary for radiosurgery. The design of this couchmount is such that it will fit most linear accelerators with only slight modifications to the couchmount adapter assembly.

The cass Couchmount System has six axes of adjustment which allows for easy setup with the Linac couch/gantry system. An additional feature of the system is a unique laser measurement apparatus for precisely measuring an isocenter of a target volume for Linac-based radiosurgery/stereotactic radiotherapy. These two features also allow for the correction of alignment errors during treatment planning setup, such as errors inherent in the use of room lasers and errors due to couch shifts during patient positioning. It will also give an index of gantry sag or misalignment.

Most commercially available stereotactic headrings can be mounted to the cass Couchmount System by the use of a stereotactic frame holder made specifically for the headring. Although most headrings are similar, each has a slightly different adapter plate which rigidly holds the headring. The stereotactic localization features of most frames are similar, differing mainly in the organization of the frame's coordinate system and its mechanical dimensions.

This couchmount system is substantially equivalent to the couchmounts manufactured by F.L. Fischer and Radionics, Inc. The advantages of this couchmount system are the 6 axes of movement which allow for compensation for couch movement due to patient weight, the laser measurement system for accurate alignment to an isocenter, and an *in vivo* portal film method for verification. The system is designed for ease of use by the physicists who would normally do the setup and collimator beam profile measurements. MIDCO, through its appropriate consultants and instructors, will give the necessary on-site instructions for installation, measurements and quality control for the couchmount system. Each institution, with its radiation oncologists and radiation physicists, is ultimately responsible for accurate measurements and gathering of data for the use of this system.

SUMMARY OF THE SAFETY AND EFFECTIVENESS OF THE CASS LINAC RADIOSURGERY COUCHMOUNT SYSTEM

INTRODUCTION

Linac Radiosurgery is a method for the delivery of a high, controlled dose of radiation to a target volume within the head. The Linac Radiosurgery technique as originally described by Colombo, et al, 1985, and Hartmann, et al, 1985, requires the use of a rigid tertiary x-ray collimator system which is affixed to the Linear Accelerator for the purpose of controlling the collimation of x-ray beams. These systems have also required a means for rigid fixation of the patient's head for positioning, alignment and controlled delivery of focused radiation beams during the delivery of a high dose of ionizing radiation in single or multiple fractions. Most manufacturers of Radiosurgery hardware provide these two major components as parts of their radiosurgery systems. MIDCO has previously developed and obtained 510-K clearance for a system of radiosurgery collimators and floorstand (see K894263/A). As an additional complement to the system, MIDCO has recently developed a couchmount stereotactic frame positioning system which is the subject of this summary.

HISTORICAL BACKGROUND - PREDICATE DEVICES

Historically, several Linac-based techniques have been used for the delivery of high-energy photon beams as a means for radiosurgery/stereotactic radiotherapy. These various methods have been well reviewed by Podgorsak, et al., 1992, and, as therein noted, the system of multiple co-planar arcs is by far the most prevalent. These techniques have also varied with regard to the method of stereotactic head fixation (patient support) during treatment, wherein the aim is to accurately align a target volume (isocenter in the patient's head or body part) within the centers of rotation of the couch/gantry coordinate system of the linear accelerator. The most common methods employed include fixation of the stereotactic head frame to the radiotherapy couch ("Couch-Mount Systems"), or fixation to a rigid floorstand mounted in the revolving floor plate of the Linac radiotherapy couch ("Floorstand Systems") (see Podgorsak, 1992; Lutz, et al., 1988; and Colombo, et al, 1992). In the practice of the art, it is generally accepted that accuracy requirements for delivery of a radiation beam to a target volume isocenter should have fractions of a millimeter of accuracy, and some authors of floorstand systems have reported such accuracy in mechanical localization (see Friedman, 1989; Lutz, et al., 1988; and Winston and Lutz, 1988). In addition, floorstand systems have generally relied upon the use of phantom test targets placed at a given stereotactic coordinate, and then placed at the center of rotation of the Linac couch/gantry system. The Linac is then used to take test target x-rays with the couch and gantry in several different positions of rotation for the purpose of accurately aligning the stereotactic reference system (see Lutz, et al., 1988). Until recently, couchmount systems have generally not been as accurate as floorstand systems, and have relied upon fixed room laser lights projected on a phantom carriage device (see Fischer system device as described by Hartmann et al.,1985) for target localization within the Linac couch/gantry coordinate system.

Although head fixation to a floorstand mounted in the Linac floor turret has historically been regarded by many as the most reliable and accurate method, it greatly limits the accessibility to the patient's head. This is particularly noticeable for lesions in the posterior portions of the head which frequently require that the patient be treated in the prone position when using such floorstand-based systems. In addition, floorstand-based systems require that the gantry of the linear accelerator be specially rigged to protect against the possibility of accidental collision of the gantry with the floorstand during the execution of any treatment plan (see Lutz, et al, 1988). Couchmount systems, on the other hand, have the advantage of being able to treat a given patient with the potential of a full 360 degrees of gantry rotation and, thereby, allow the patient to be treated in a natural supine position, whilst also avoiding the need for gantry collision protection (see Colombo, et al, 1985, and Podgorsak, 1992).

The couchmount systems are desirable for the above-noted reasons, yet they have a disadvantage in that patient head fixation and stabilization within the coordinate system of the couch/gantry rotations of the Linac are generally not as accurate as floorstand-based systems. This is due to sagging and/or tilting of the couch which can occur in couchmount systems when weight, as weight of a patient's body, is applied to the couch tabletop after initial alignment. Such positional shifts are a source of error in couchmount systems. Attempts to solve this problem have been by cumbersome methods of bracing the couch tabletop (see Colombo, 1992), or the reliance on fixed, intersecting laser beams arranged as intersecting lines and emitted from laser alignment devices attached to the ceilings and walls of the room in which the linear accelerator is housed for the purpose of referencing the origin of the Linac couch/gantry axes of rotation. Such laser lights are commonly employed in the art of radiation therapy, and are also known in the art to frequently shift and require recalibration or alignment, and can introduce yet another source of error in target alignment within the couch/gantry coordinate system. Furthermore, such laser beams are usually 2–3 mm wide and may limit the accuracy of alignment because of the thickness of the alignment beams and parallax. This visual method relies on the use of positional laser beams for alignment and has the limitations noted herein. MIDCO has patented a technique which uses lasers for <u>precise measurement of distances</u> as a means for target volume localization within the couch/gantry coordinate system of a Linac-based radiosurgery/stereotactic radiotherapy system. This method is also a supplement to the aforementioned visual laser alignment method for couchmount systems.

Some manufacturers of radiosurgery equipment have also employed various techniques of target alignment verification (see Podgorsak, 1992, pp. 31-32). These alignment verification methods generally consist of the use of x-ray verification techniques. MIDCO utilizes a recognized *in vivo* portal x-ray imaging technique whereby images from the linear accelerator are taken with the patient on the treatment couch. We shall also describe this x-ray verification method as a part of this summary (see Serago, et al., 1991).

MIDCO, as other manufacturers, employs tertiary x-ray collimators in its radiosurgery system. These tertiary collimators consist of a set of 12, varying in bore diameters of 2.5 mm over a range of 12.5 to 40 mm. The collimator set consists of cerrobend filled inserts with a slightly tapered bore to correspond to beam divergence. The collimator inserts fit into the end of a tubular collimator housing that is attached to a collimator base plate which, upon being attached to the Linac gantry, can be fitted and variably adjusted to align the collimator tube to the central beam of the Linac. This collimator set is substantially equivalent to other collimators on the market (510-K #K894263A). As designed, the collimator base permits the taking of portal x-rays with the collimators in place.

THE COUCHMOUNT SYSTEM

The Couchmount (patient support) System consists of:

a) A couchmount adapter assembly
b) A couchmount head holder and precision positioner
c) A couchmount Precision Localization Box
d) A couchmount laser measurement apparatus
e) A couchmount test target assembly

These components are herein summarized and are designed for quick attachment and disconnection to the end of the couch table and support system. The couchmount head holder and precision positioner consist of a micrometer controlled assembly having 6 axes of adjustment (x, y, z, rotation, skew and tilt) which is adaptable to hold a variety of stereotactic frames. The Precision Localization Box fixes to the stereotactic frame and references the stereotactic frame's coordinate system. It can be used with room laser lights that are reflected off its sides (which have millimeter etchings) for visual alignment of stereotactic coordinates. It can also be used with anterior–posterior and lateral portal x-rays for *in vivo* stereotactic target confirmation (see Serago et. al. 1991; Siddon and Barth 1987). A unique feature of the Precision Localization Box is its use in conjunction with a patented laser measuring system (U.S. Patent number 5,553,112) that allows direct measurement of stereotactic targets. Lutz type phantom test targets are also possible with the system (Lutz, et al., 1988).

The laser measurement system is a patented improvement over other methods of stereotactic alignment, which rely primarily on the use of room laser lights or the use of phantom targets for referencing "hidden" stereotactic targets. This system has the additional advantage of permitting direct, and precise measurements of stereotactic targets by the use of a laser measuring device, having fractions of a millimeter of accuracy, which is attached to the Linac gantry and emits a laser beam which projects onto and reflects off the surfaces of a Precision Localization Box for the purpose of precisely measuring and centering isocenters within the couch/gantry coordinate system.

The **cass** Linac Radiosurgery Collimators and Couchmount Patient Support System are mechanically designed to allow quick and consistent assembly. In regular use, the system is assembled and tested with the Lutz-type phantom test target method to confirm the geometric accuracy of the system and target localization prior to any treatment.

SUMMARY OF TEST DATA

The overall accuracy of the mechanical movements and positioning of a given Linac radiosurgery system is of primary importance in the accurate delivery of a radiation dose to a target structure. For this reason, it was important to test the geometric accuracy of the Linac used to test the **cass** Collimators and Couchmount System. The initial accuracy of the test Linac for radiosurgery, a Varian 2100 C, was determined to be ≤ 1.0 mm for gantry rotational intersection with the rotational axis of the couch in all positions. The collimators and couchmount were positioned according to guidelines in the **cass** Radiosurgery Hardware Setup Manual, and tests were done to determine the geometric accuracy of the complete radiosurgery system. The system was regularly assembled and disassembled over a one year period during which the system was tested.

The Lutz method (1988) of testing radiation beam accuracy was used to evaluate the collimators and couchmount as they would be integrated into similar Linacs for configuring a radiosurgery system. In these tests, random phantom targets throughout the extremes of the coordinate system of the Leksell frame and BRW frame were setup using the Lutz-type phantom pointer to simulate test targets. Radiographic images of the test targets were taken from various couch/gantry positions and examined for x, y, and z displacements (Dx, Dy, Dz). In summary, this data showed an error range of 0.48 mm ± 0.262 mm.

The Lutz phantom test is designed to test the mechanical accuracy of a given Linac radiosurgery system. These test results, using the **cass** collimators and couchmount, are an index of the accuracy that similarly configured systems would be capable of, given proper setup and configuration. These test results are considerably better than the established guidelines (≤1 mm) of many institutions using radiosurgery (see Podgorsak, et al. 1992) and substantially equivalent to predicate devices.

The overall accuracy of the system was tested according to guidelines recommended by Lutz, et al. (1988) and Serago, et al. (1991), in which a sheet of dosimetry film is placed in a humanoid phantom, and a target point is radiated and the isocenter of the multiple intersecting beams is compared to the target position of the phantom target point indicator. The target point is localized with both angiographic and CT imaging techniques. The accuracy of the Linac System used in these phantom tests was determined to be 0.5 mm ± 0.3 mm. This test is a composite test of the overall accuracy of the Linac radiosurgery system and incorporates errors due to CT image slice thickness and the accuracy of the angiographic localizer for determining hidden targets.

Port film tests were done according to the method recommended by Serago, et. al. (1991) (representing the Fischer System). The Laser Measurement System in conjunction with the Precision Localization Box was also used to check target alignment. Using this method, A-P and lateral port films were taken at various predetermined target sites set with the aid of the Laser Measurement System. The difference between the intended target and calculated target using this *in vivo* technique were determined. Total alignment error for *in vivo* verification tests was 0.492 mm +/- 0.155 mm.

These test results are within the established published guidelines as noted by representatives of the Fischer System (Hartmann, et al., 1985, and Serago, et al., 1991), and the Radionics System (Winston and Lutz, 1988). Representatives of the Fischer System have reported localization accuracy of +/- 0.5 mm and representatives of the Radionics System have reported a localization accuracy of 0.5 mm +/- 0.2 mm. The **cass** Linac Couchmount System is substantially equivalent to predicate devices, and, with proper setup and quality control, is safe and effective. To date, a number of patients have been treated with this system, which has worked well in all instances.

The **cass** Couchmount System is designed to attach to the linear accelerator manufactured by Varian and Associates of 3045 Hanover Street, Mail Stop H-055, Palo Alto, California, 94304.

The system is adaptable to other linear accelerators by some slight modifications of the couch-mount adaptor assembly. MIDCO submits a "Linac Site Information" questionnaire to each site for specifics on their linear accelerator and stereotactic hardware to assure proper configuration of the hardware for a specific site.

MIDCO provides each user institution with installation manuals for their cass Radiosurgery System and instructions on commissioning its system. A MIDCO installation team is present for the initial setup and alignments of the radiosurgery system, and specific training and instructions are given to the site's designated physicists and users. MIDCO personnel can be present during the first clinical case to insure proper use of the system. The user institution is encouraged to communicate to MIDCO any concerns it may have regarding the use of the System, and MIDCO provides the user with report forms for notifying MIDCO of any perceived problems or concerns.

Bibliography to the Summary of Safety and Effectiveness

A) Articles related to Comparative Specifications of (Similar) Substantially Equivalent Devices

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B) Articles related to Comparative *in vivo* Data (Hardware related studies)

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Leavitt, D., et al., "Dynamic Field Shaping to Optimize Stereotactic Radiosurgery," Int J Radiat Oncol Biol Phys, 19, Supplement 1: 133 (1990).

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Note: There are now numerous articles in various radiotherapeutic and neurosurgical journals which relate to the methods and indications for radiosurgery, its principles and practice.