

JUL 12 1999



Medical Instrumentation and Diagnostics Corporation

K991336

510(k) Summary

As required by section 807.92(c)

Trade Name: **BodyLoc™**
Whole Body Stereotactic Localizer
System For Radiotherapy

Common Name: Body Stereotactic Frame and Immobilizer

Classification Name: X-ray Radiation Therapy System (accessory)

Reference: Per 21 CFR Section 892.550

Proposed Regulatory Class: II

Submitter: MIDCO®

5995 Mira Mesa Blvd., Suite B

San Diego, CA 92121

TEL. (619) 558-5880

FAX. (619) 558-5883

Contact: Tyrone L. Hardy, M.D.

Date of Preparation: April 13, 1999

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Identification of Predicate Devices

- a) Elekta Instrument AB
18140 Smokesignal Drive
San Diego, CA 92127
Product Name: Stereotactic Body Frame
510(k) Number: K960338
- b) Elekta Instrument AB
St. Larsgatan 8
Linköping, SW S-582 24
Product Name: Accessories to the Stereotactic Body Frame
510(k) Number: K970291
- c) Howmedica Inc. (Leibinger)
359 Veteran Blvd.
Rutherford, NH 07070-2584
Product Name: Extracranial Radiotherapy System
510(k) Number: K982463

Device Description

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. Stereotactic localization fiducials are positioned in the sides and base of the BodyLoc™ and the localization system is continuous from the head to mid-thigh regions. The BodyLoc™ is supplied with a software program for calculation of BodyLoc™ stereotactic coordinates from scanner images. Software is functional on IBM or IBM-compatible PC computers with Microsoft® Windows 95. Targets within the system can be aligned by use of the coordinate indicators on the sides of the frame and the moveable arc localizer. Immobilization is achieved by the use of a vacuum mold system or polyurethane foam mold for posterior (the part of the body nearest the frame base) areas and a thermoplastic body mold to cover large body surfaces in the ventral or anterior plane. The BodyLoc™ has quality assurance markers in its base which are used to aid in system set-up and in verifying the accuracy of the coordinate alignment and target calculations.

Intended Use

The BodyLoc™ is a body stereotactic frame device designed for stereotactic diagnostic localization and stereotactic radiotherapy of localized targets.

Summary of Substantial Equivalence

MIDCO®'s body localizer (the BodyLoc™) is substantially equivalent in function, use, and performance to the stereotactic body frame predicate devices manufactured by Elekta Instruments AB and Howmedica (Leibinger). The dimensions of the BodyLoc™ are similar and it can be used with CT and MR imaging systems. The differences in the design of the BodyLoc™ to predicate devices include the following:

- a) Body localization with an uninterrupted fiducial indicator and coordinate localization system that extends continuously from the head to the pelvis/mid-thigh; and means for both,
- b) Anterior and posterior immobilization over wide body areas for reliable repositioning and immobilization.

Technological Characteristics

The technological characteristics of the BodyLoc™ in comparison to predicate and legally marketed devices is provided in the following table entitled "Substantially Equivalent Devices Comparison Table".

Summary of Performance Data and Conclusions

MIDCO® developed tests to evaluate the functionality of its BodyLoc™ System as a stereotactic localization device. Since the BodyLoc™ is a stereotactic immobilization system with an internal imaging fiducial localization system, it was necessary to test the accuracy of the fiducial system. Additional tests were developed to test the axial imaging localization algorithm used with the fiducial system. Tests were also developed to evaluate the fiducial localization system in relation to quality assurance reference markers embedded in the base of the localizer at known stereotactic frame z-axis levels. The imaging fiducial localization algorithm was then tested against a scanner screen measurement method. The latter screen coordinate measurement method can also be used as an additional target quality assurance method.

A series of Monte Carlo tests and test calculations and measurements of multiple targets throughout the BodyLoc™ using various axial scan slice thicknesses resulted in an overall accuracy range substantially equivalent to that of predicate devices. The material used to manufacture the frame was evaluated under normal use, and the frame material was evaluated for radiation attenuation when irradiated with different MeV LINACs. These studies also demonstrated that the BodyLoc™ was safe and accurate in positioning a patient in relation to the coordinate reference system.

Table 5 Substantially Equivalent Devices Comparison

SUBSTANTIALLY EQUIVALENT DEVICES COMPARISON TABLE			
Features	Stereotactic Body Frame® (Elekta) K960338,K970291	Extracranial Radiotherapy System (Howmedica/Fischer) K982463	BodyLoc™ (MIDCO®)
1. Anterior body form (immobilization)	No	No	Yes
2. Posterior body form (immobilization)	Yes	Yes	Yes
3. Dimensions	1000cm L x 50cm W x 20cm H	2000cm L x 50cm W x 18cm H	1125cm L x 55cm W x 19cm H
4. Construction Material/Attenuation Coefficient (cm ⁻¹)	Laminate of wood and plastic 0.0467 cm ⁻¹	Carbon fiber composite Approximately 0.5 cm ⁻¹	Polycarbonate 0.029 cm ⁻¹
5. Method of suppressing diaphragmatic movements	Breastplate	Breastplate	Thermoplastic mold over chest and abdomen
6. Stereotactic fiducial markers built into frame	Yes	Yes	Yes
7. Fixation	Vacuum pillow	Skeletal and/or Vacuum pillow	Vacuum pillow or foam mold and Thermoplastic Mold
8. Imaging studies	CT scan before each treatment Also MR	Single CT scan before treatment Also MR	CT and/or MR scan before each treatment
9. Treatment modality	Photon linear accelerator	Photon linear accelerator	Photon linear accelerator
10. Radiation delivery	Usually 8-10 noncoplanar fixed beams	Usually 4-6 noncoplanar fixed beams	Usually 4-10 noncoplanar fixed beams
11. CT Localization error in the transversal plane. (x-axis, y-axis)	Mean 3.1 mm	Mean 0.98 ± 0.22 mm	Mean 0.5095 ± 0.1058 mm
12. CT localization error in the longitudinal plane (z-axis)	Range, 2-7 mm	Range, 0.9-3.5 mm	Range, 0.41-2.10 mm
13. LINAC Set-up Error	Approximately 10 mm	Approximately 2.5 mm	Approximately 3.0 mm
14. Proposed clinical applications	Intraabdominal, intrathoracic therapeutic targets	Spinal, paraspinal and other extracranial therapeutic targets	Head, neck, thoracic, pelvis, abdominal therapeutic targets
15. Immobilization	Non-Invasive	Invasive/Non-Invasive	Non-Invasive

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JUL 12 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Tyrone L. Hardy
Medical Instrumentation and Diagnostics Corp.
5995 Mira Mesa Blvd, Suite B
San Diego, California Suite B

RE: K991336
BodyLoc Whole Body Stereotactic
Localizer System for Radiotherapy
Dated: April 15, 1999
Received: April 19, 1999
Regulatory Class: II
21 CFR 892.5050/Procode: 90 IYE

Dear Mr. Hardy:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,

CAPT Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indications For Use

510(k) Number: K991336

Device name: BodyLoc™

Whole Body Stereotactic Localizer System For Radiotherapy

Indications For Use:

This is to certify that the BodyLoc™ Whole Body Stereotactic Localizer System For Radiotherapy, as submitted under the above referenced 510(k) number, is indicated for use as a precision patient immobilization and positioning system for the purpose of performing diagnostic localization and fractionated stereotactic radiotherapy/ radiosurgery treatment. It is substantially equivalent to similar devices which are used to position the body during stereotactic radiotherapy of various body lesions. The decision and conditions under which the system is to be used is made by the patient's managing physician(s).

This form submitted by:

MIDCO®
5995 Mira Mesa Blvd., Suite B
San Diego, CA 92121
TEL. (619) 558-5880
FAX. (619) 558-5883

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter-Use _____
(Per 21 CFR 801.109)

Colin M. Pollard
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K991336

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