K013391

JAN 11 2002

510(k) SUMMARY

1. Applicant:	Medical Intelligence Medizintechnik GmbH	
2. Address:	Feyerabendstrasse 13 - 15	
	86830 Schwabmünchen	
	Germany	
3. Contact Persons:	Cornelia Damsky Tel:	(203) 323-7535
	Christian Müller Tel:	+49 (0) 8232 9692-0
4. Preparation Date:	October 10, 2001	
5. Device Submitted:	BodyFIX and accessories	
6. Proprietary Name:	BodyFIX	
7. Common Name:	BodyFIX	
8. Classification Name:	Accelerator, Linear, Medical for use in fixation of a patient's body part for stereotactic diagnostic localization and stereotactic radiotherapy. Product Code IYE	
9. Substantial Equivalence:	The BodyFIX system is substantially equivalent in terms of intended use to the following currently marketed devices: Med-Tec Inc.'s BodyFIX System, Elekta Instrument AB's Stereotactic Body Frame and accessories and Midco's BodyLoc. The characteristics of this device are similar to those of the predicate devices identified on the comparison chart, which is provided with this premarket notification submission.	
10. Device Description:	The BodyFIX system is a patient positioning and immobilization device for use with radiotherapy, radiosurgery, sonography, surgery/CAS, imaging neurosurgery and brachytherapy treatments of extracranial targets. The five principal parts of the system include the vacuum cushion, fixation sheet, vacuum supply, target positioner and localizer, and carbon fiber baseplate.	
11. Intended Use:	The BodyFIX is intended for patient positioning and immobilization, stereotactic diagnostic localization and stereotactic radiotherapy of extracranial targets	

12. Legally-Marketed Predicate Device: Med-Tec Inc.'s BodyFIX System, Elekta Instrument AB's Stereotactic Body Frame and Midco's BodyLoc

13. Performance Data: No performance data is required for this Class II device nor requested by the Food and Drug Administration (Office of Device Evaluation). A data base search has been performed to evaluate any adverse effects of the device that is currently marketed.

No data submitted for section 807.92 6[(b)(1)(2)(3c)].

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 11 2002

Medical Intelligence Medizintechnik GmbH
Christian Muller
Feyerabendstrasse 13 - 15
86830 Schwabmunchen
Germany

Re: K013391
Trade Name: Bodyfix
Regulation Number: 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: October 12, 2001
Received: October 15, 2001

Dear Mr. Muller:

We have reviewed your Section 510(k) premarket 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 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.

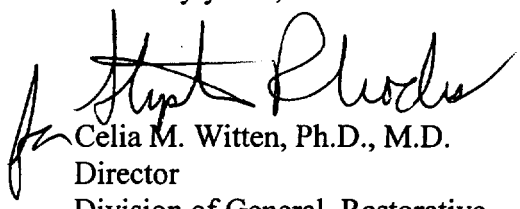
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. 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). 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,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K013391

BodyFIX

INDICATIONS FOR USE

This product is intended for use by radiologists and surgeons for:

- Patient positioning and immobilization
- Stereotactic diagnostic localization
- Stereotactic radiotherapy of extracranial targets

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K013391