K030439

MAY - 8 2003

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:	February 7, 2003
5. Device Submitted:	VBH HeadFIX™ and accessories
6. Proprietary Name:	VBH HeadFIX™
7. Common Name:	HeadFIX™
8. Classification Name:	Accelerator, Linear, Medical for positioning and repositioning of the patient's head for stereotactic diagnostic localization and stereotactic radiotherapy. Product Code IYE
9. Substantial Equivalence:	The VBH HeadFIX™ is substantially equivalent in terms of intended use to the following currently marketed devices: Radionics Gill-Thomas-Cosman (GTC) Relocatable Head Holder, Orfit Industries' Raycast Immobilization Systems Hardware and Thermoplastic Materials, and BrainLAB's Brain Mask System.
10. Device Description:	The VBH HeadFIX™ is a fixation device for cranial stereotactic radiotherapy and radiosurgery. The major parts of the system include the Vacuum Pump, Vacuum Cushion, Target Positioner Screens and Baseplate, Post Set, and Cranial Localizer.
11. Intended Use:	The VBH HeadFIX™is intended for positioning and immobilization of the head and neck, stereotactic diagnostic localization and stereotactic radiotherapy of cranial targets.
12. Legally-Marketed Predicated Device:	Radionics Gill-Thomas-Cosman (GTC) Relocatable Head Holder, Orfit Industries' Raycast Immobilization Systems Hardware and Thermoplastic Materials, and BrainLAB's Brain Mask System.

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 database 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

MAY - 8 2003

Ms. Cornelia Damsky
Regulatory Consultant
Cornelia Damsky, Inc.
56 Westcott Road
STAMFORD CT 06902

Re: K030439
Trade/Device Name: HeadFIX
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: 90 IYE
Dated: February 7, 2003
Received: February 11, 2003

Dear Ms. Damsky:

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

K030439

Page__ of ___

510(k) Number (If known): K030439

Device Name: VBH HeadFIX

Indications For Use:

This product is intended for use by radiologists and surgeons for:
Positioning and repositioning of the patient's head;
Stereotactic diagnostic localization; and
Stereotactic radiotherapy of cranial targets

(PLEASE DO NOT WRITE BEELOW 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)

David A. Lagomarsino

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K030439