

K081935

OCT 07 2008

## 510(k) Summary

### In Compliance with 21 CFR Section 807.92(c)

#### 1. General Provisions

Device Trade Name: Stereotactic Head and Neck Localizer

Common Name: Head and Neck Fixation System

Owner Name and Address: Aktina Medical Physics Corporation  
360 North Route 9 W  
Congers, New York, 10920  
Phone: 845-268-0101  
Fax: 845-268-1700  
Registration Number: 2436865

#### 2. Classification

This device is classified as a class II device according to 21 CFR 892.5050, "Medical charged-particle radiation therapy system." The product code is IYE.

#### 3. Predicate Devices

- 1) VBH HeadFix, K030439, manufactured by Medical Intelligence Medizintechnik, Schwabmunchen, Germany
- 2) X-Plan-2 and Head and Neck Localizer (HNL), K991237 and GTC Headholder, K934523, manufactured by Radionics Software Applications, Inc, Burlington, MA
- 3) Stereotactic Mask System, CT/X-Ray Localizer, and Target Positioner, K945903, K954861, and K073018, BrainLAB AG, Heimstetten, Germany

#### **4. Description**

The Aktina Head and Neck Stereotactic Localizer, Part Number 50-100, is used for the localization and fixation of patients undergoing stereotactic radiotherapy and radiosurgery of the cranial area, as well as radiotherapy of the head and neck area. Fixation is accomplished via two components: a customized Dental Tray that with the aid of slight vacuum suction fixes to the roof of the patient's mouth, and a customized head and neck support. Localization is accomplished via two components: a hardware component which comprises of a Stereotactic Fiducial Frame that is positioned over the patient's treatment area while being accurately interfaced to the Dental Tray, and a software component that reads the patient's Computed Tomography (CT) imaging series and determines the coordinate system of the patient within the fiducial frame. The Fiducial Frames are used during the patient's initial CT and then as a setup target box for each treatment thereafter.

The following are optional components of the system:

- shoulder restraints which can be employed for head and neck treatments,
- a table adapter which allows for manual angulations to level the system within the treatment room in order to remove any angular errors induced by the treatment couch,
- a software tool that rotates the patient's imaging series (used for treatment planning) to remove any angular errors incurred during the initial CT imaging.

#### **5. Intended Use**

This product is used for patients who require external beam stereotactic radiation therapy of the head and neck region or radiosurgery of the cranial region. The system provides cranial and head and neck fixation and stereotactic localization with automatic software fiducial localization. It is intended to be used during both Computed Tomography (acquisition of the imaging series used for the patient's treatment plan) and each of the patient radiation treatments.

#### **6. Technological Characteristics**

The Aktina Medical Physics' Stereotactic Head and Neck Localizer Software has the same technological characteristics as: the VBH HeadFix manufactured by Medical Intelligence Medizintechnik, the X-Plan-2 and Head and Neck Localizer (HNL) / GTC Headholder manufactured by Radionics Software Applications, Inc., and the Stereotactic Mask System, CT/X-Ray Localizer, and Target Positioner, K945903 manufactured by BrainLAB AG. All of these systems accomplish non-invasive cranial and head and neck immobilization as well as tumor localization with the patient in a supine position by using:

- a. A carbon fiber base board adapted to the CT or treatment patient table,
- b. A dental impression tray or face mask attached to a rigid support apparatus for fixation of the patient's cranium,
- c. A fiducial localizing frame to provide initial CT study data and a target box for patient set-up during LINAC treatment,
- d. A computerized determination of the target position based on the localizing frame data.

**7. Performance Standards and Data**

The FDA under Section 514 of the Food, Drug and Cosmetic Act has not established performance standards for this product

Hardware and software specification testing have been performed on the Stereotactic Head and Neck Localizer to show that the verification, validation and safety requirements have been met.

**8. Biocompatibility**

The Aktina Medical Corporation Stereotactic Head and Neck Localizer and its associated components have been shown to be biocompatible per the requirements of the FDA's Blue Book Memorandum #G95-1, entitled Use of International Standard ISO-10993-1, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing" for surface devices in contact with the skin or a mucosal membrane with a contact duration of less than 24 hours.

**9. Summary of Substantial Equivalence**

This device is similar in design and intended use, technological, physical, and performance characteristics to the predicate devices. No new issues of safety or effectiveness are introduced by using this device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

OCT 07 2008

Mr. Tony Spaccarotella  
Director, QA/RA  
Aktina Medical Physics Corporation  
360 North Route 9W  
CONGERS NY 10920

Re: K081935

Trade/Device Name: Stereotactic Head and Neck Localizer  
Regulation Number: 21 CFR 892.5050  
Regulation Name: Medical charged-particle radiation therapy system  
Regulatory Class: II  
Product Code: IYE  
Dated: September 15, 2008  
Received: September 16, 2008

Dear Mr. Spaccarotella:

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 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), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Joyce M. Whang, Ph.D.  
Acting Director, Division of Reproductive,  
Abdominal, and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

Section 4

Indications for Use

510(k) Number (if known): K081935

Device Name: Stereotactic Head and Neck Localizer

Indications for Use:

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Prescription Use √  
(Part 21 CFR 801 Subpart D)

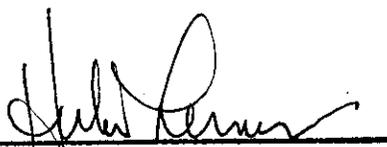
AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF  
NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)  
Division of Reproductive, Abdominal,  
and Radiological Devices

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