K103616

JAN 25 2011

510(k) Summary

In Compliance with 21 CFR Section 807.92(c)

1. General Provisions

Device Trade Name:	Pinpoint Stereotactic Head and Neck Localizer
Common Name:	Head and Neck Fixation System
Owner Name and Address:	Aktina Medical Corporation 360 North Route 9 W Congers, New York, 10920 Phone: 845-268-0101 Fax: 845-268-1700 Registration Number: 2436865
Contact Person:	Tony Spaccarotella
Date:	December 3 2010

2. Classification

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

3. Predicate Device

Stereotactic Head and Neck Localizer, K081935, manufactured by Aktina Medical Corporation, 360 North Route 9 W, Congers, New York, 10920

4. Description

The Aktina Pinpoint 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.

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 Pinpoint Stereotactic Head and Neck Localizer is identical to the predicate device, except that an additional source has been added for both the mouthpiece and its materials and the mouthpiece vacuum port is external to the patient rather than inside the mouth. The new mouthpiece and the original mouthpiece are otherwise identical in form, fit and function.

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 specification testing has been performed to show that the verification, validation and safety requirements have been met.

8. Biocompatibility

The Aktina Medical Corporation Pinpoint Stereotactic Head and Neck Localizer and its associated components, including the new mouthpiece, 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 to the predicate device in design and intended use, as well as technological, physical, and performance characteristics. 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
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Mr. Tony Spaccarotella
Director Quality Assurance/Regulatory Affairs
Aktina Medical Corporation
360 North Route 9W
CONGERS NY 10920

JAN 25 2011

Re: K103616
Trade/Device Name: Pinpoint 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: December 8, 2010
Received: December 10, 2010

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 class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). 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 Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S Pastel

Mary Pastel, ScD.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Section 4

Indications for Use

510(k) Number (if known): K103616

Device Name: Pinpoint 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)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

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