K131313

510(k) Summary

In Compliance with 21 CFR Section 807.92(c)

1. General Provisions

Device Trade Name:	Active Breathing Coordinator
Common Name:	Patient Monitor
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

AUG 0 7 2013

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) Active Breathing Coordinator (ABC), 510(k) No. K003330, Aktina Medical Corporation, 360 North Route 9W, Congers, NY 10920
2) Respiratory Gating System, Cat. No. AK-733, 510(k) No. K031385, Anzai Medical Company, Ltd., 3-6-25 Nishi-Shinagawa, Shinagawa-ku, Tokyo 141-0033 Japan

4. Description

This Traditional 510(k) describes product enhancements for the Active Breathing Coordinator (ABC). The ABC is a flow meter device that allows radiation therapy patients to graphically observe the volume of air that enters and exits their lungs on a computer monitor. The patients are coached prior to the treatment and instructed to hold their breath when the volume of air entering or exiting their lungs reaches a predefined threshold volume. Accurate and reproducible timing of the breath hold period is aided by a patient controlled balloon valve which is connected to the flow meter device. Radiation is only delivered during the breath hold period. Radiation may be delivered by the therapist manually turning the beam on and off, or automatically by using the Elekta Limited Response™ gating interface (FDA 510(k) clearance number K123808, available separately from Elekta, Ltd., Crawley, UK).

5. Intended Use

The Active Breathing Coordinator is indicated for use when there is a need to reduce the anatomical movement in the thorax and abdomen caused by breathing and cardiac motion. It is intended for breath-hold (BH) during simulation and delivery of External Beam Radiation Therapy (EBRT) using photons, in single or multiple fractions, administered via static and/or dynamic delivery processes, in any and all areas of the body where such treatment is indicated. It also provides electrical prompts and status information for the Elekta Limited Response™ gating interface when automated gating of the linac is used.

The Active Breathing Coordinator is specifically indicated for:

a. Breast tumors, including total and partial breast irradiation techniques, where immobilized anatomy provided by deep inspiration breath-hold (DIBH) allows critical organ sparing, such as decreasing radiation dose to heart, lung and other surrounding normal tissue.

b. Lung cancers and other thoracic tumors (such as esophagus, lymphoma, and metastatic lesions) where immobilized anatomy provided by DIBH allows critical organ sparing, including reducing both dose and volume of irradiated normal tissue, and enabling potential reduction of tumor target margins. Also included is the use of linac-based Stereotactic Radiosurgery (SRS) and Stereotactic Radiation Therapy (SRT) that may be employed to treat such lesions.

c. Liver tumors, where immobilized anatomy provides critical organ sparing, including reducing both dose and volume of irradiated normal tissue enabling potential reduction of tumor target tissue margins. Also included is the use of linac-based SRS and SRT that may be employed to treat such lesions.

d. Pancreatic tumors, where immobilized anatomy allows critical organ sparing including reducing both dose and volume of irradiated normal tissue, enabling potential reduction of tumor target tissue margins. Also included is the use of linac-based SRS and SRT that may be employed to treat such lesions.

6. Technological Characteristics

The enhanced ABC uses the same technology as its predicate device from Aktina Medical, the ABC K003330, with one exception. The enhanced ABC also supports automated gating of the treatment beam from a linear accelerator that contains the Elekta Ltd. Response linac gating interface option. The enhanced ABC electrically prompts the Response to interrupt the linac beam and resume it at the appropriate times during the patient's breathing cycle. It also displays status information from the Elekta Response. The technology to support the Elekta Response is the same as the second predicate device listed above, the AK-733 Respiratory Gating System from Anzai Medical Company, Ltd. (K031385), which also electrically

prompts a linear accelerator to turn the beam on and off at appropriate times during the patient's breathing cycle. The significant technology characteristics of the ABC are:

a. Laptop personal computer software and external display monitor with graphical user interface.
b. Patient respiratory kit with an in-line transducer and balloon valve for air volume monitoring during patient breathing and lung volume stability during breath hold periods. The balloon valve is controlled pneumatically.

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 enhanced ABC to show that the verification, validation and safety requirements have been met.

8. Biocompatibility

The patient contact components of the enhanced ABC are identical to the patient contact components of the ABC K003330, except that over-the-counter prism reading glasses may be used in place of a mirror system to allow the patient to see the monitor in a supine position. These components have been shown to be biocompatible for surface devices in contact with a skin or 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.

Specifically, the enhancements for the ABC are substantially equivalent to the predicate devices as follows:

Type of Modification:	ABC (This Application)	Predicate ABC K003330	Predicate Anzai, AK-733, K031385	Substantially Equivalent To:
Technology	Automatic and Manual Linac Gating	Manual Linac Gating only	Automatic and Manual Linac Gating	Anzai, AK-733, K031385
Update of Indications	Limit Respiratory-Related Organ Motion with Specific Indications	Limit Respiratory-Related Organ Motion	Limit Respiratory-Related Organ Motion	ABC, K003330

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

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

August 7, 2013

Re: K131313
Trade/Device Name: Active Breathing Coordinator
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: May 1, 2013
Received: May 9, 2013

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact 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/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Michael D. O'Hara for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K131313

Device Name: Active Breathing Coordinator

Indications for Use:

The Active Breathing Coordinator is indicated for use when there is a need to reduce the anatomical movement in the thorax and abdomen caused by breathing and cardiac motion. It is intended for breath-hold (BH) during simulation and delivery of External Beam Radiation Therapy (EBRT) using photons, in single or multiple fractions, administered via static and/or dynamic delivery processes, in any and all areas of the body where such treatment is indicated. It also provides electrical prompts and status information for the Elekta Limited Response™ gating interface when automated gating of the linac is used.

The Active Breathing Coordinator is specifically indicated for:

a. Breast tumors, including total and partial breast irradiation techniques, where immobilized anatomy provided by deep inspiration breath-hold (DIBH) allows critical organ sparing, such as decreasing radiation dose to heart, lung and other surrounding normal tissue.
b. Lung cancers and other thoracic tumors (such as esophagus, lymphoma, and metastatic lesions) where immobilized anatomy provided by DIBH allows critical organ sparing, including reducing both dose and volume of irradiated normal tissue, and enabling potential reduction of tumor target margins. Also included is the use of linac-based Stereotactic Radiosurgery (SRS) and Stereotactic Radiation Therapy (SRT) that may be employed to treat such lesions.
c. Liver tumors, where immobilized anatomy provides critical organ sparing, including reducing both dose and volume of irradiated normal tissue enabling potential reduction of tumor target tissue margins. Also included is the use of linac-based SRS and SRT that may be employed to treat such lesions.
d. Pancreatic tumors, where immobilized anatomy allows critical organ sparing including reducing both dose and volume of irradiated normal tissue, enabling potential reduction of tumor target tissue margins. Also included is the use of linac-based SRS and SRT that may be employed to treat such lesions.

Indications for Use

510(k) Number (if known): K131313

Device Name: Active Breathing Coordinator

Prescription Use ___√___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

Michael D. O'Hara

(Division Sign Off)
Division of Radiological Health
Office of *In Vitro* Diagnostic and Radiological Health

510(k) K131313