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

April 5, 2017

Anzai Medical Co., Ltd.
% Ms. Carole Carey
President
C3-Carey Consultants, LLC
9451 Ellsworth Court
FULTON MD 20759

Re: K170719
Trade/Device Name: AZ-733VI Respiratory Gating System
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle Radiation therapy system
Regulatory Class: II
Product Code: LHN
Dated: March 8, 2017
Received: March 9, 2017

Dear Ms. Carey:

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 Industry and Consumer Education 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" (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 Industry and Consumer Education 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,

For

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K170719

Device Name

AZ-733VI Respiratory Gating System

Indications for Use *(Describe)*

Respiratory Gating System AZ-733VI is intended to be used with diagnostic X-ray or radiation therapy systems to gate these devices on and off when target points of the patient's respiratory cycle are within preset limits.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

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1. Submitter

Anzai Medical Co., Ltd.
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Tokyo 141-0033, Japan

Phone: +81-3-3779-1611
Fax: +81-3-3779-6606

Contact Person Name: Naoya Iwasaki

Date Prepared: March 8, 2017

2. Device

Name of Device:	AZ-733VI Respiratory Gating System
Common or User Name:	Respiratory Gating System
Classification Name:	Medical Charged-Particle Radiation Therapy System (21 CFR 892.5050)

Regulatory:	Class II
Product Code:	LHN

3. Predicate Device

AZ-733VI Respiratory Gating System, K160432

4. Device Description

The Respiratory Gating System AZ-733VI employs a respiratory sensor which can be fixed directly to or near to a patient, and detects the respiratory motion changes according to the type of sensor, the Load Cell (standard component), the Laser Sensor (option component) or the IRP Sensor (option component).

The signal from the sensor is primarily amplified at the Amp Box which is attached to each Respiratory Sensor and sent to the Sensor Port as an analog signal. At the Sensor Port, the analog signal is coarsely adjusted manually, converted to digital signal, smoothed by moving-average method and processed to detect a respiratory phase. Then, as a respiratory information, the respiratory waveform and the respiratory phase are sent to the Application on the Personal Computer via the Relay Box.

The Application performs the fine adjustment of the selected respiratory waveform by the user manually or automatically. The user also sets a Gate signal output condition and selects a mode for the method of generating Gate signal. This Gate signal is output to external equipment (image diagnostic equipment such as a whole body CT equipment, linear accelerator system and radiotherapy equipment) from the Relay Box or the Sensor Port when those respiratory signals reach the preset conditions set by the user. The status of the Gate signal ON and OFF is also displayed on the LCD Display. The Application has a function of managing patient information. This function involves the input, registration, referring, revision and delete of patient information. The Application also provides the function of recording, playback, referring and output by a text file format of respiratory information and Gate signal ON/OFF status as well as Beam signal ON/OFF status.

5. Indications for Use

The Respiratory Gating System AZ-733VI is intended to be used with diagnostic x-ray or radiation therapy systems to gate these devices on and off when target points of the patient's respiratory cycle are within preset limits.

The Indications for Use statement for the modified device is identical to the predicate

device.

6. Comparison of Technological Characteristics with the Predicate Device

The subject device and the predicate device are based on the same technological elements except for the following:

- Addition of ABLE which utilizes wireless Bluetooth technology

7. Non-clinical Performance Data

The following performance data ware provided in support of the substantial equivalence determination.

(1) Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the AZ-733VI, consisting of standard components and optional components. The system complies with the IEC 60601-1:2012, IEC 60601-1-6:2013, IEC 62366:2007 and IEC 60825-1:2007 standards for safety and the IEC 60601-1-2:2007 standard for EMC.

(2) Software Verification and Validation Testing

Software verification and validation testing were conducted and documented in accordance with the recommendation by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submission for Software Contained in Medical Devices". The software for the subject device is considered as a "major" level of concern as well as that of the predicate device, since a failure or latent flaw in the software could directly result in serious injury or death to the patient or user.

8. Conclusions

From the nonclinical tests, the subject device is as safe and effective as the predicate device, and performs as well as or better than the predicate device.

9. Validity of applying special 510(k)

Based on the New 510(k) Paradigm flowchart on the Attachment 1 of "The New 510(k) Paradigm Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications" provided by CDRH, validity of applying special 510(k) for the subject device was checked.
As the result, it is determined that the modified subject is submitted as special 510(k).

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Acknowledgment Letter

3/9/2017

Carole C. Carey, President
C3-Carey Consultants, LLC
9451 Ellsworth Court
Fulton, MD 20759
UNITED STATES

Dear Carole C. Carey:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has received your submission. This submission has been assigned the unique document control number below. All future correspondence regarding this submission should be identified prominently with the number assigned and should be submitted to the Document Control Center at the above letterhead address. Failure to do so may result in processing delays. If you believe the information identified below is incorrect, please notify the Program Operations Staff at (301) 796-5640.

Submission Number: K170719
Received: 3/9/2017
Applicant: Anzai Medical Co., Ltd.
Device: Anzai Respiratory Gating System

We will notify you when the review of this submission has been completed or if any additional information is required. For information about CDRH review regulations and policies, please refer to http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm.

Sincerely yours,

Center for Devices and Radiological Health