



June 27, 2025

EmpNia Inc.
% Janice Hogan
Partner
Hogan Lovells US LLP
1735 Market Street Floor 23
Philadelphia, PA 19103

Re: K243900

Trade/Device Name: eMotus Respiratory Motion Management System
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical Charged-Particle Radiation Therapy System
Regulatory Class: Class II
Product Code: LHN, IYE
Dated: December 18, 2024
Received: December 19, 2024

Dear Janice Hogan:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See

the DICE website (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

A handwritten signature in black ink, reading "Lora D. Weidner". The signature is fluid and cursive. A large, light blue "FDA" watermark is visible in the background behind the signature.

Lora D. Weidner, Ph.D.
Assistant Director
Radiation Therapy Team
DHT8C: Division of Radiological
Imaging and Radiation Therapy Devices
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Submission Number (if known)

K243900

Device Name

eMotus Respiratory Motion Management System

Indications for Use (Describe)

The EmpNia eMotus system is used to measure and record the patient's respiratory waveform to aid with respiratory-synchronized image acquisition or reconstruction during CT diagnostic imaging or radiation treatment planning procedures, where there is a risk of respiratory motion compromising the resulting image.

The EmpNia eMotus system is used to derive and communicate a Gate signal to aid with organ position verification for radiation therapy treatment using CT or Xray imaging by monitoring the patient's respiratory waveform during the image acquisition, where there is a risk of respiratory motion compromising the resulting image.

The EmpNia eMotus system is used to derive and communicate a Gate signal to aid with radiation therapy treatment, where there is a risk of respiratory motion compromising the resulting treatment accuracy.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

"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
EmpNia Inc.'s eMotus Respiratory Motion Management System
K243900

Submitter

EmpNia Inc.
4500 Lakeview Dr.
Edina, MN 55424
Phone: +1 206-650-6885
Contact Person: Manojeeet Bhattacharya, CEO

Date Prepared: June 26, 2025

Device Information

Trade Name: eMotus Respiratory Motion Management System

Common or Usual Name: Respiratory gating system

Classification Name: Medical charged-particle radiation therapy system

Regulation Number: 892.5050

Product Code: LHN, IYE

Predicate Device

AZ-733VI Respiratory Gating System (K170719)

Device Description

The eMotus Respiratory Motion Management System ("eMotus system") is designed to monitor patient respiratory motion and to provide information about this respiratory motion to an external medical device system, such as a radiation therapy delivery device (TDD) or a diagnostic imaging device (DX). The main components of the eMotus system include:

- Sensor pad with optical fiber sensors,
- Optical fiber cables,
- Optical transceiver,
- Data acquisition computer with eMotus software application,
- Communication modules for compatible external systems, and
- Cables to allow data transmission between the components.

The sensor pad is a single-use, disposable component with an adhesive backing that is placed directly on the patient's thorax or abdomen. The sensor pad is attached to optical fiber cables that connect to the optical transceiver, which collects optical signal data based on deflection of the sensors in response to respiratory motion. The transceiver digitizes the data and transmits it to the eMotus computer, which visualizes the data as a waveform that can be highlighted when the waveform amplitude reaches a user-specified threshold or the patient's respiratory cycle reaches a user-specified phase. The user can utilize the respiratory threshold and phase information to manually control an external TDD or DX system.

The user can also connect the eMotus system directly to a compatible external system by using the communication module. When connected to an external TDD or DX, the eMotus system supports the following functions (as applicable given the functions of the external system):

- Threshold-gated therapy delivery: Automatic gating (turning on / off) of the radiation treatment beam based on user-set parameters for the amplitude of the respiratory waveform.
- Phase-gated therapy delivery: Automatic gating (turning on / off) of the radiation treatment beam based on user-set parameters for the phase of the respiratory waveform cycle.
- Retrospective four-dimensional planning scan: Delivery of the respiratory waveform to an imaging device to synchronize the waveform data with the scan data, enabling retrospective four-dimensional reconstruction of the imaging session for use in treatment planning.
- Prospective four-dimensional planning scan: Automatic patient's respiratory waveform are within preset limits, which is used to disable the radiation beam automatically.

The eMotus device is an ancillary device and does not provide stand-alone therapy or diagnostic information.

Intended Use / Indications for Use

The EmpNia eMotus system is used to measure and record the patient's respiratory waveform to aid with respiratory-synchronized image acquisition or reconstruction during CT diagnostic imaging or radiation treatment planning procedures, where there is a risk of respiratory motion compromising the resulting image.

The EmpNia eMotus system is used to derive and communicate a Gate signal to aid with organ position verification for radiation therapy treatment using CT or Xray imaging by monitoring the patient's respiratory waveform during the image acquisition, where there is a risk of respiratory motion compromising the resulting image.

The EmpNia eMotus system is used to derive and communicate a Gate signal to aid with radiation therapy treatment, where there is a risk of respiratory motion compromising the resulting treatment accuracy.

Summary of Technological Characteristics

The technological characteristics of the subject and predicate device are compared in the following table.

	Predicate device: Anzai Respiratory Gating System (AZ-733VI) (K170719)	Subject Device: EmpNia eMotus (K243900)	Comparison
Classification	21 CFR 892.5050	21 CFR 892.5050	Same
Product Code	IYE	LHN, IYE	Similar
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 EmpNia eMotus system is used to measure and record the patient's respiratory waveform to aid with respiratory-synchronized image acquisition or reconstruction during CT diagnostic imaging or radiation treatment planning procedures, where there is a risk of respiratory motion compromising the resulting image. The EmpNia eMotus system is used to derive and communicate a Gate signal to aid with organ position verification for radiation therapy treatment using CT or Xray imaging by monitoring the patient's respiratory waveform during the image acquisition, where there is a risk of respiratory motion compromising the resulting image. The EmpNia eMotus system is used to derive and communicate a Gate signal to aid with radiation therapy treatment, where there is a risk of respiratory motion compromising the resulting treatment accuracy.	Similar

	Predicate device: Anzai Respiratory Gating System (AZ-733VI) (K170719)	Subject Device: EmpNia eMotus (K243900)	Comparison
System components	• Load Cell with Elastic Fixing Belt, Laser Sensor, IRP Sensor • Amp Box • Sensor Port • Personal computer with proprietary software application • Relay Box • Cables to connect system components	• Optical fiber sensor pad with adhesive backing • Optical fiber cables • Transceiver • Data acquisition computer with proprietary eMotus software application • Communication modules • Cables to connect system components	Similar
Sensor location	Chest or abdomen	Chest or abdomen	Same
Patient contacting parts / materials	Elastic fixing belt (materials not publicly specified)	Adhesive backing of sensor pad (Avery Dennison MED5051 adhesive tape)	Different
Sensor technology	Load cell, laser, or IRP	Fiber optic strain sensing	Different
Compatible external system types	Diagnostic imaging systems and radiation therapy systems	Diagnostic imaging systems and radiation therapy systems	Same
Gating methods	Manual or automatic	Manual or automatic	Same
Latency from data acquisition to Gate signal output	≤ 50ms (normal gate mode)	≤ 50ms	Same
Motion monitoring accuracy	Not publicly specified	Verified in comparative testing to predicate device showing nearly identical signals in normal and deep breathing conditions.	Similar
Power requirements	AC 100 - 240 V, 50 / 60 Hz, 200 W	AC 100 - 240 V, 50 / 60 Hz, 160 W	Similar
Operating environment	Temperature: 10 - 35 °C Humidity: 30% - 75%	Temperature: 10 - 40 °C Humidity: 30% - 85%	Similar

As shown in the above table, the system components of the predicate device are similar to the subject device. In particular, both devices have a sensor, signal transmission components, components for initial processing and digitization of the sensor data, a computer with proprietary software application for signal processing, system control, and display of the respiratory waveform, components for communication with an external system, and cables to connect the system components. In addition, both the subject device and the predicate device are labeled for use with external systems, including radiation therapy systems and diagnostic imaging systems, and to generate a Gate signal (based on waveform amplitude thresholds or respiratory cycle phase) and output the Gate signal to a compatible external system. Although the particular compatible systems may vary, both devices interact with the external systems for the same functions.

The primary technological difference between the subject device and the predicate device is the sensor technology. The eMotus system uses optical fiber sensors placed on the patient, whereas the predicate device uses a strain gauge placed on the patient and also has options for sensors that utilize lasers or infrared technology and do not touch the patient. However, in both devices the sensors respond to changes in the motion of the body surface during respiration, and in both devices the sensor data is converted to a respiratory waveform that supports both threshold and phase gating during radiation therapy or imaging. Therefore, the difference in sensor technology does not raise different questions of safety or effectiveness. Other technological differences, such as patient-contacting materials, power requirements, software programs, and system-specific operational instructions, also do not raise different questions of safety or effectiveness. Furthermore, as described below, performance testing of the subject device supports that the eMotus system and the predicate device have a similar safety and effectiveness profile.

Performance Data

The following testing was performed to support substantial equivalence:

- Biocompatibility: The system complies with standards for cytotoxicity (ISO 10993-5:2009), sensitization (ISO 10993-10:2021), and irritation (ISO 10993-23:2021).
- Electrical safety and electromagnetic compatibility (EMC): The system complies with standards for electrical safety (IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, IEC 60601-1:2005/AMD2:2020, ANSI/AAMI ES60601-1:2005/A2:2021) and EMC (IEC 60601-1-2:2014/AMD1: 2020). Device-specific performance criteria were met during EMC immunity testing. The system also passed specific immunity testing of wireless power transfer and cellular 5G emissions.
- Software and cybersecurity: The subject device passed software verification and validation testing, and documentation was provided in accordance with the FDA Guidance, “Content of Premarket Submissions for Device Software Functions” (2023). Cybersecurity testing and risk assessment verified adequate mitigation of cybersecurity risks.
- Human factors: Summative human factors testing validated that the subject device can be used safely and effectively by its intended users.

- Bench performance: The subject device's performance for its intended use was verified in bench performance testing, including comparison of the device's waveform to the predicate device as well as simulated use testing to assess signal latency, device functionality in different usage scenarios, and consistency in performance across multiple sensors. The comparative evaluations showed that the subject and predicate devices produce equivalent respiratory waveforms. The simulated use testing supported that the subject device meets its requirement for signal latency; has stable dynamics and peak frequency in infant and adult phantoms at normal and fast breathing frequencies; correctly pauses gating, sets the gate to off, and alerts the user when there is irregular breathing; and shows consistent, repeatable, and reproducible behavior over multiple sensors.

The above testing supports that the subject device is as safe and effective as the predicate device.

Conclusions

The eMotus system has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. The minor differences in indications do not alter the intended use of the device . In addition, the minor technological differences between the eMotus system and its predicate devices do not raise any different questions of safety or effectiveness and do not affect its safety and effectiveness when used as labeled. Performance testing demonstrates that the eMotus system is as safe and effective as the predicate device. Thus, the eMotus system is substantially equivalent.