November 3, 2025

Zap Surgical Systems, Inc.
Junyi Wang
Director, Regulatory Affairs
590 Taylor Way
San Carlos, California 94070

Re: K250392
Trade/Device Name: ZAP-X Radiosurgery System (ZAP-X)
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical Charged-Particle Radiation Therapy System
Regulatory Class: Class II
Product Code: IYE, MUJ
Dated: February 11, 2025
Received: February 12, 2025

Dear Junyi Wang:

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.

FDA's substantial equivalence determination also included the review and clearance of your Predetermined Change Control Plan (PCCP). Under section 515C(b)(1) of the Act, a new premarket notification is not required for a change to a device cleared under section 510(k) of the Act, if such change is consistent with an established PCCP granted pursuant to section 515C(b)(2) of the Act. Under 21 CFR 807.81(a)(3), a new premarket notification is required if there is a major change or modification in the intended use of a device, or if there is a change or modification in a device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process. Accordingly, if deviations from the established PCCP result in a major change or modification in the intended use of the device, or result in a change or modification in the device that could significantly affect the safety or effectiveness of the device, then a new premarket notification would be required consistent with section 515C(b)(1) of the Act and 21 CFR 807.81(a)(3). Failure to submit such a premarket submission would constitute adulteration and misbranding under sections 501(f)(1)(B) and 502(o) of the Act, respectively.

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,

Lora D. Weidner
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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K250392

Device Name

ZAP-X Radiosurgery System (ZAP-X)

Indications for Use *(Describe)*

The ZAP-X Radiosurgery System is intended to provide treatment planning and image-guided stereotactic radiosurgery and precision radiotherapy for tumors, lesions and conditions in the brain, head and neck when radiation treatment is indicated.

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
PRAStaff@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

Nov. 3, 2025

APPLICANT:

ZAP Surgical Systems, Inc.
590 Taylor Way
San Carlos, CA 94070
United States

APPLICANT CONTACT:

Junyi Wang
Director, Regulatory Affairs
junyi@zapsurgical.com
+1 (678) 580-8188

SUBJECT DEVICE

Trade Name	ZAP-X Radiosurgery System
Model	ZAP-X
Common Name	Medical charged-particle radiation therapy system
Regulation Number	21 CFR 892.5050
Product Code	IYE, MUJ
Classification Name	Accelerator, Linear, Medical
Classification	Class II

PREDICATE DEVICES AND REFERENCE DEVICE

Predicate Device	ZAP-X Radiosurgery System (K211663)
Reference Device	Akesis Galaxy (K190844)

DEVICE DESCRIPTION SUMMARY

The self-shielded ZAP-X® Radiosurgery System is a computer-controlled system for planning and delivering non-invasive stereotactic radiosurgery for tumors, lesions and conditions in the brain, head, and neck when radiation treatment is indicated. The system is self-shielded for ionizing radiation, allowing it to be installed in a non-bunker environment. A linear accelerator mounted on a dual-gantry provides a therapeutic radiation source, and a kV imaging system is used to locate and track the treatment target throughout the treatment.

Key Subsystems and Accessories of the ZAP-X Radiosurgery System

- **ZAP-Axon® Treatment Planning System:** the dedicated software application used to create, optimize, and review treatment plans for the ZAP-X Radiosurgery System. It provides the functionalities for the import, registration, and fusion of imaging studies, the delineation of target volumes and organs at risk (OARs), the calculation and optimization of the radiation dose, and the creation of planning reports. The application is installed on dedicated workstations that are directly connected to the other ZAP-X components.
- **Treatment Delivery System:** the dedicated software application that enables loading and delivering of treatment plans on the ZAP-X Radiosurgery System. It includes the functionalities for quality assurance, loading and reviewing plans, performing automatic patient setup, reviewing image guidance results, delivering the planned dose, and producing delivery reports. It also manages the interlocks of the system.
- **Linear Accelerator:** The ZAP-X utilizes a linear accelerator to produce therapeutic x-rays.
- **Circular Beam Collimation:** The ZAP-X provides circular fields of various sizes up to 25 mm to enable the dose to be conformed to the target volume.
- **Dual Gantry:** The ZAP-X utilizes a unique, dual gantry system to enable the radiation to be delivered from multiple, non-coplanar points. The structure of the gantries also provides radiation shielding, generally negating the need for any additional shielding when installing the system.
- **KV Imaging:** The ZAP-X includes a kilovoltage x-ray imaging system that is used for image-based patient alignment and tracking.
- **DoseGuard® Patient Safety System:** The ZAP-X includes an integrated transit dosimetry system, referred to as DoseGuard. This system provides an extra layer of patient safety by comparing measured and planned exit fluence and pausing the delivery if a deviation is detected.
- **Patient Table:** The ZAP-X utilizes a patient table to position the patient for treatment. The patient is immobilized with a thermoplastic mask or the PinZ Patient Immobilizer.
- **PinZ® Patient Immobilizer:** an optional accessory designed for rigid, non-invasive head immobilization. The device consists of a frame that is attached to the patient table and fixation pins that are affixed to the patient's head to minimize voluntary and involuntary patient movement and maintain the target position throughout the treatment session.

INDICATIONS FOR USE

The ZAP-X Radiosurgery System is intended to provide treatment planning and image-guided stereotactic radiosurgery and precision radiotherapy for tumors, lesions and conditions in the brain, head and neck when radiation treatment is indicated.

TECHNOLOGICAL CHARACTERISTICS COMPARISON

The subject device has been developed by modifying the predicate device ZAP-X Radiosurgery System (K211663). Modifications to the subject device do not impact safety or effectiveness.

The modifications being addressed in this 510(k):

- Treatment Planning System
  - Introduced the trade name ZAP-Axon Treatment Planning System with a new graphical user interface.
  - Updated image fusion user interface, added support for additional views and automated fusion of multiple series.
  - Expanded the number and type of supported contours.
  - Refactored and optimized path planning algorithms, and updated collision models to reflect the conformal table insert.
  - Optimized processing speed by general algorithm refactoring, including dose calculation and dose optimization.
  - Enabled treatment plan comparison.
  - Added support for custom CT density tables.
- Treatment Delivery System
  - Introduced Gyroscopic Correction, an optional feature that uses image guidance results to update the gantry position to correct for patient rotations.
  - Reduced processing time and increased robustness of patient tracking and alignment (recall number: Z-1742-2022).
  - Implemented minor updates and corrections to collision detection and detour logic (recall number: Z-2639-2025).
- Cybersecurity
  - Implemented cybersecurity enhancements, including OS and network security updates and executable/configuration checks.
- Hardware
  - Replaced the flat table insert with the conformal table insert.
  - Increased the maximum table load from 135 kg to 210 kg.
  - Replaced table railings with brackets for securing straps.
  - Added an emergency shell release that enables opening the shell without electrical power.
  - Increased maximum nominal dose rate to 1800 MU/min.
  - Added supplementary shielding to small areas.

- Accessories
  - Updated the DoseGuard housing and mounting and assigned a new trade name.
  - Introduced the PinZ Patient Immobilizer as an optional accessory.
- Labeling
  - Revised labeling to reflect the design changes listed above.

The subject and predicate devices have the same indications for use, operating principles, and similar technological characteristics. The changes do not raise different questions of safety or effectiveness. A summary of the technological characteristics of the subject device compared to the predicate device is provided below, and a second table is provided for the optional accessory compared to the reference device (K190844):

Subject	**Predicate Device** **ZAP-X Radiosurgery System (K211663)**	**Subject Device** **ZAP-X Radiosurgery System (K250392)**
Product Code	IYE	IYE, MUJ
Regulation Number	21 CFR 892.5050	Same
Rx/OTC	Rx	Same
Indications for use	The ZAP-X Radiosurgery System is intended to provide treatment planning and image-guided stereotactic radiosurgery and precision radiotherapy for tumors, lesions and conditions in the brain, head and neck when radiation treatment is indicated.	Same
Treatment Site	Brain, head, and neck	Same
Target Patient Population	The system is intended for use for treatments in the head and neck on patients that are between the size of a 5th percentile female to a 95th percentile male.	Same
Number of Treatment sessions	Single fraction or a short course of hypofractionation (2-5 sessions)	Same
Moveable Treatment Beam	Yes – Two degree of freedom gantry	Same
Shielding for Ionizing Radiation	Self-shielding	Similar Added supplementary shielding in small areas, overall performance remains equivalent.

Subject		Predicate Device ZAP-X Radiosurgery System (K211663)	Subject Device ZAP-X Radiosurgery System (K250392)
Treatment Beam Energy		3MV nominal photon beam energy	Same
Real-Time Dosimetry (Ion Chamber based dose monitoring systems)		Yes	Same
Treatment Planning Software		Software subsystem	Similar New graphical user interface (GUI) New trade name: "*ZAP-Axon®* *Treatment Planning System*" Updated image fusion user interface, added support for additional views and automated fusion of multiple series. Expanded the number and type of supported contours. Refactored and optimized path planning algorithms, and updated collision models to reflect the conformal table insert. Optimized processing speed by general algorithm refactoring, including dose calculation and dose optimization. Enabled treatment plan comparison. Added support for custom CT density tables.
Treatment Delivery Software		Integrated	Similar New Gyroscopic Correction feature. Reduced processing time and increased robustness of patient tracking and alignment. Implemented minor updates and corrections to collision detection and detour logic.
Accessory		MV Imager (Disposable Dosimeter)	Similar. DoseGuard® (new appearance and trade name for MV Imager) with manufacturability; no change to intended use or functionality.
Optional Accessory		N/A	PinZ® Patient Immobilizer (new optional accessory)
Performance Specification	**Treatment Beam Energy**	3MV nominal photon beam energy	Same
	Percentage Depth Dose:	PDD (10cm) = 40% ± 2%	Same
	Dose rate (in MU/min)	1500±10% MU/min at 450mm SAD	Maximum nominal dose rate 1800 ±10% MU/min at 450mm SAD.

Subject		Predicate Device ZAP-X Radiosurgery System (K211663)	Subject Device ZAP-X Radiosurgery System (K250392)
	Penumbra at depth of maximum dose	25 mm field size: 2.25 mm	25 mm field size: 2.5 mm
	Overall System Patient Positioning Accuracy	within ± 1mm	Same
	Treatment Beam	Available circular beam sizes: diameters of 4.0 mm, 5.0 mm, 7.5 mm, 10.0 mm, 12.5 mm, 15.0 mm, 20.0 mm, and 25.0 mm at isocenter	Same
Predetermined Change Control Plan (PCCP)		N/A	PCCP included in the submission to add 3mm beam size at isocenter.

Subject	Reference Device Akesis Galaxy (K190844)	Optional Accessory PinZ Patient Immobilizer
Indications for Use	The Akesis Galaxy Rotating Gamma System, is a teletherapy device intended for the stereotactic irradiation of human head structures.	This optional accessory is intended to be used with the ZAP-X Radiosurgery System, to provide rigid immobilization of the head during stereotactic radiosurgery and precision radiotherapy when indicated by the physician.
Head Frame Material	Anodized aluminum	Similar
Cranial Pins Material	Ti 6Al-4V	Similar
Head Frame Patient Fixation	Four Pins	Similar
Sterilization	Cleaning and Autoclave Sterilization	Similar

NON-CLINICAL AND CLINICAL TESTS SUMMARY

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

The subject device (ZAP-X Radiosurgery System) has undergone formal design verification and design validation testing including electrical safety, electromagnetic compatibility, radiation safety, software verification and validation, system verification and validation, biocompatibility, usability and cybersecurity

testing. New functionality, such as gyroscopic correction, was verified and validated against pre-defined acceptance criteria established to ensure safe and effective performance. Improvements to existing functionalities, such as image fusion, dose calculation, dose optimization, image guidance and collision detection, were tested against acceptance criteria that were based upon the criteria for the predicate device. This testing was enhanced and expanded where appropriate. In all respects, test results indicated that the defined acceptance criteria were met and the system, its components and accessories meet their specifications and are appropriate for their intended use.

The new optional accessory to ZAP-X Radiosurgery System (PinZ Patient Immobilizer), in addition to design verification and validation, has also undergone cleaning and sterilization validation, biocompatibility testing, and usability testing.

A formative clinical study for the optional accessory PinZ Patient Immobilizer was conducted early in development to identify preliminary use-related risks, evaluate and refine critical tasks, and inform design improvements. It was followed by a summative usability validation study for the ZAP-X Radiosurgery System and PinZ Patient Immobilizer, conducted in accordance with IEC 62366 and FDA Guidance Applying Human Factors and Usability Engineering to Medical Devices to verify that the device performs as intended for the intended users, uses, and use environments.

Use of Consensus Standards

The following list of FDA-recognized, voluntary consensus standards were utilized in the design and evaluation of the subject device's safety and effectiveness as compared to the predicate.

Standard	Name
IEC 60601-1:2020	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2:2020	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – Requirements and tests
IEC 60601-1-3 2021	Medical electrical equipment –Part 1-3: General requirements for basic safety and essential performance – Collateral Standard: Radiation protection in diagnostic X-ray equipment
IEC 60601-1-6:2020	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability
IEC 62366-1:2020	Medical devices – Application of usability engineering to medical devices
IEC 60601-2-1:2020	Medical electrical equipment—Part 2-1: Particular requirements for the basic safety and essential performance of electron accelerators in the range 1 MeV to 50 MeV
IEC 60601-2-68:2014	Medical electrical equipment – Part 2-68: Particular requirements for the basic safety and essential performance of X-ray-based image-guided radiotherapy equipment for use with electron accelerators, light ion beam therapy equipment and radionuclide beam therapy equipment
IEC/TS 60601-4-2:2024	Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems
IEC 60825-1:2014	Safety of laser products – Part 1: Equipment classification and requirements
IEC 60976:2007	Medical electrical equipment – Medical electron accelerators – Functional performance

Standard	Name
	characteristics
IEC 61217:2011	Radiotherapy equipment – Coordinates, movements and scales
IEC 62083:2009	Medical electrical equipment – Requirements for the safety of radiotherapy treatment planning systems
IEC 62304:2006/AMD 1:2015	Medical device software – Software life-cycle processes
IEC 81001-5-1:2021	Health software and health IT systems safety, effectiveness and security - Part 5-1: Security - Activities in the product life cycle
ISO 14971:2019	Medical devices- Application of risk management to medical devices
ISO 10993-1:2018	Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process.
ISO 10993-5:2009	Biological evaluation of medical devices - part 5: Tests for in vitro cytotoxicity
ISO 10993-10:2021	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
ISO 10993-11:2017	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
ISO 10993-23:2021	Biological evaluation of medical devices - Part 23: Tests for irritation
ISO 17664-1:2021	Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices - Part 1: Critical and semi-critical medical devices

PREDETERMINED CHANGE CONTROL PLAN (PCCP)

The predetermined change control plan (PCCP) for the device specifies anticipated modifications to the ZAP-X System software and hardware to support an additional circular beam size with 3.0 mm diameter.

The PCCP provides a description of the device's planned modification, the modification protocol to test, verify, and validate the modification; and an impact assessment and implementation plan which together will ensure the modified device is as safe and effective as the predicate.

A summary of the modifications, testing methods, performance requirements, validation activities, and user communication is provided in the table below:

Planned Modification	Testing Methods, Validation Activities and Performance Requirements	Communication to Users
One additional circular beam size with a 3.0 mm diameter. This change will include changes to hardware (a new collimator wheel) and software (TPS to enable commissioning and planning for the new field size and TDS to select, display and deliver the new field size).	Testing of the ZAP-Axon Treatment Planning System will include verifying the completeness of beam commissioning data for the selected collimator configuration prior to planning, and the usage of corresponding beam data for dose calculation when 3.0 mm beam size is selected. Testing of the Treatment Delivery System will include verifying the	Existing users will be notified that an upgrade is available and will require both hardware and software updates to their system. If requested, a user's system hardware and software will be upgraded and they will be provided with updated user manuals and receive training regarding commissioning and using the new 3.0 mm beam.

Planned Modification	Testing Methods, Validation Activities and Performance Requirements	Communication to Users
	collimator calibration procedure, the selection of 3.0 mm beam size when specified by the treatment plan, and the display of 3.0 mm beam size (if used) in the delivery report. Validation testing will be carried out to validate that the new field size provides clinical benefit and that planned and delivered dose volumes agree. These tests are a part of ZAP's established protocol for tests related to collimator field sizes. Additional testing will include adherence to applicable clauses of IEC 60976, IEC 62083, IEC 62304 and IEC 60601-2-1.	For new users, Labeling (including ZAP-Axon manual, treatment delivery manual, beam data manual) and marketing materials will be provided in accordance with the authorized PCCP. All users will receive training for the trade-off of using a 3.0 mm beam size and the process of properly commission the system to use the 3.0mm beam.

CONCLUSION

The principle of operation of the subject device is the same as that of the existing predicate device. Verification and validation testing demonstrated that the subject device is as safe and effective as the predicate. ZAP therefore concludes that the subject device ZAP-X Radiosurgery System is substantially equivalent to its cleared predicate device.