Zap Surgical Systems, Inc.
℅ Mr. Jim Talbot
Vice President RA/QA
590 Taylor Way, Suite A
SAN CARLOS CA 94070

July 29, 2021

Re: K211663
Trade/Device Name: Zap-X® Radiosurgery System
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: Class II
Product Code: IYE
Dated: May 28, 2021
Received: June 1, 2021

Dear Mr. Talbot:

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 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,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211663

Device Name
Zap-X® Radiosurgery System

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.

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510(K) SUMMARY

510(k) Notification K211663

GENERAL INFORMATION [807.92(a)(1)]

Applicant:
Zap Surgical Systems, Inc.
590 Taylor Way, Suite A
San Carlos, CA 94070 USA
Phone: (650) 793-8250
FAX: (650) 832-1038

Contact Person:
Jim Talbot
Vice President RA/QA
Phone: (650) 793-8250
FAX: (650) 832-1038

Date Prepared: May 28, 2021

DEVICE INFORMATION [807.92(a)(2)]

Trade Name: Zap-X® Radiosurgery System

Generic/Common Name:
Medical charged-particle radiation therapy system

Regulation Number/Classification:
21 CFR 892.5050, Class II

Classification Product Code:
IYE

510(K) SUMMARY

PREDICATE DEVICE

Company: Zap Surgical Systems, Inc.
Device: Zap-X® Radiosurgery System (K183698)

REFERENCE DEVICE

Company: ACCURAY INCORPORATED
Device: CyberKnife M6 Systems (K150873)

INDICATIONS FOR USE [807.92(a)(5)]

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.

DEVICE DESCRIPTION [807.92(a)(4)]

The subject device, a modification to the previously cleared Zap-X Radiosurgery System, is a computer-controlled system for performing non-invasive stereotactic radiosurgery that is self-shielded for ionizing radiation. A gantry-mounted linear accelerator provides the modified Zap-X System with a therapeutic radiation source, and a kV imaging system is used to locate the treatment target accurately. At the start of treatment, X-ray images of the patient skeletal anatomy serve to align the treatment target with respect to the system isocenter. During radiosurgical treatment, the kV imaging system of the modified Zap-X System tracks patient movement and adjusts the table precisely to compensate for such movement.

The subject device for which this submission is being made improves the patient tracking/alignment throughout treatment. This is the only new feature which has been implemented on the subject device differentiating it from the predicate device. There is no change to the system specifications as a result of this improvement in patient alignment – the overall system patient positioning is still within 1 mm as with the predicate device.

PREDICATE DEVICE(S) [807.92(a)(3)]

Zap Surgical Systems, Inc. asserts that the subject device, Zap-X Radiosurgery System ("Zap-X System"), is substantially equivalent to the predicate device Zap-X Radiosurgery System, cleared under 510(k) K183698. The subject device and the predicate device are medical charged-particle radiation therapy systems, falling within 21 CFR 892.5050, Product Code IYE. The subject

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device is comparable to the predicate device with respect to product labeling, intended use, anatomical sites, patient population, performance testing, technological characteristics, and safety characteristics. The subject device is also appropriately comparable to Accuray Cyberknife M6 System (reference device) cleared under 510(k) K150873.

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COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICES [807.92(a)(6)]

The technological characteristics of the subject device and the predicate device cleared under Zap-X Radiosurgery System (K183698) and reference device all have similar features and components. All three systems utilize a Linac system to generate the treatment beam.

The subject device and the predicate, and the reference device all use a collimator to control the treatment beam size. The treatment beam sizes offered with the subject device are identical to the predicate device and within the ranges offered by the reference device, CyberKnife. Moreover, all three systems deliver treatment beams from a variety of directions. In addition, all three systems have a patient table to support and position the patient during treatment. The subject device, predicate device, and reference device Accuray CyberKnife have a KV imaging system to monitor patient movements allowing accurate delivery of radiation to the treatment target. All systems have control consoles and interface software to control and monitor treatment planning and treatment delivery systems. All systems include capabilities for patient tracking. Like the primary predicate and CyberKnife, the subject device uses the patient skeletal anatomy to align the treatment target with respect to the system isocenter. All three systems use the kV imaging system to track patient movement and adjust the table precisely to compensate for such movement during treatment. All three systems were extensively tested for electrical safety, electromagnetic compatibility and other applicable state-of-the-art standards for medical electrical equipment, electron accelerators, and radiotherapy equipment.

The primary difference in technological features between the predicate Zap-X System and the subject device is that the latter has implemented a number of minor design changes. While none of the minor design changes implemented in the subject device would require a new 510(k) submission, the multitude of changes that have been implemented since the clearance of the predicate device warrant a submission at this time. The subject device is identical to its predicate with respect to design in that both systems are intended to treat lesions of the head. Finally, the subject device was demonstrated to meet the requirements for radiation leakage and provide protection from radiation to the operator and general public identical to that of the predicate Zap-X Radiosurgery System as well as the reference CyberKnife device within a radiation-shielded vault.

SUBSTANTIAL EQUIVALENCE

The subject device is identical to the primary predicate device previously cleared on February 25, 2019 (K183698). The two devices have identical intended use, i.e., the planning and performance of image-guided stereotactic radiosurgery and precision radiotherapy. In

510(K) SUMMARY

addition, the proposed brain, head, and neck targets to be treated by the subject device are identical to the treatment targets in the primary predicate device and the reference Accuray CyberKnife device.

Detailed comparisons of the proposed Zap-X Radiosurgery System to the primary predicate Zap-X System as well as the reference CyberKnife device are provided in the following table.

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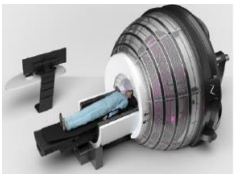
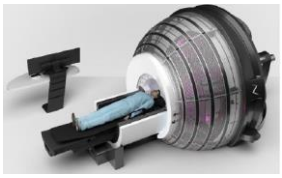
SUBSTANTIAL EQUIVALENCE TABLE

Table 12.1. Substantial Equivalence Table

Feature	**Subject Device** Zap-X Radiosurgery System	**Primary Predicate Device** Zap-X Radiosurgery System (K183698)	**Reference Device** Cyberknife M6 Systems (K150873)	Analysis of Differences
Product Image				None
Regulation Number	21 CFR 892.5050 Medical charged-particle radiation therapy system	21 CFR 892.5050 Medical charged-particle radiation therapy system	21 CFR 892.5050 Medical charged-particle radiation therapy system	None
Regulatory Class	II	II	II	None
Classification Product Code	IYE	IYE	IYE	None
Indications for Use	Identical to the primary predicate device	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.	The Cyberknife M6 Systems are indicated for treatment planning and image-guided stereotactic radiosurgery and precision radiotherapy for lesions, tumors, and conditions anywhere in the body when radiation treatment is indicated.	Reference device treats entire body while subject and predicate devices treat the head, neck and brain only

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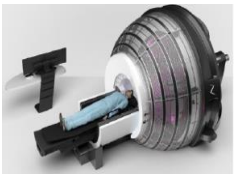
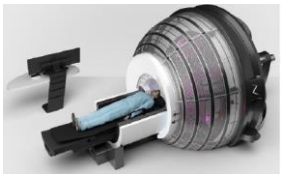
Feature	**Subject Device** Zap-X Radiosurgery System	**Primary Predicate Device** Zap-X Radiosurgery System (K183698)	**Reference Device** Cyberknife M6 Systems (K150873)	Analysis of Differences
Product Image				None
Product Description/ Design	Identical to the primary predicate device	The zap-X Radiosurgery Systems (Zap-X System) is a robotic radiosurgery system consisting of a compact Linac mounted on a dual axis rotational gantry. The gantry parts also serve as radiation shields enabling the system to operate without a bunker. The Zap-x positions with patient with the target at the isocenter by moving the patient table under kV image guidance. The source is then rotated isocentrically around the patient to deliver radiation from various angles.	The CyberKnife M6 System utilizes a compact X-bancd Linac mounted on a robotic manipulator arm. The patient is positioned by a couch under kV image guidance and the source is moved around the patient and radiation is delivered from various angles.	Subject and predicate devices treat patient within shielded system while reference device treats patient within shielded vault or bunker (radiation exposure to the user and general public are equivalent for all three systems)
Safety Features	Identical to the primary predicate device	The Zap-x has been designed to include the following: -E-stop buttons to enable the user to stop machine motion and radiation -Interlocks to prevent	-Contact detection sensor at the distal end of the secondary collimator housing on the linac and on the back of robot arm.	None

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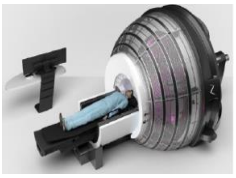
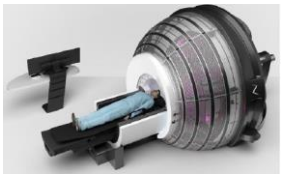
Feature	**Subject Device** Zap-X Radiosurgery System	**Primary Predicate Device** Zap-X Radiosurgery System (K183698)	**Reference Device** Cyberknife M6 Systems (K150873)	Analysis of Differences
Product Image				None
		improper system usage -Password and physical key access/radiation control -Proximity scanners that ensure system motion and radiation only occur when the area around the system is clear -A laser scanning proximity detector to detect and prevent collisions with the collimator -A software collision predication model that utilizes a standard patient envelope to predict potential collisions prior to system movement.	-Contact with the sensor causes an Emergency Stop (E-STOP) condition halting all motion of the system. -Safety Zones: There is a safety zone around the patient and the treatment couch; size is user selectable based on individual patient sizes (small, medium, or large). The dynamic safety zone is designed to encompass the entire patient body and always lies within the fixed safety zone.	

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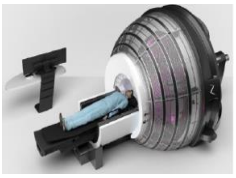
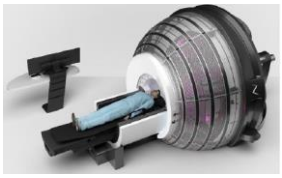
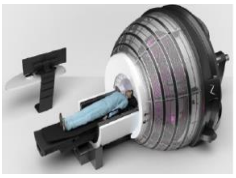
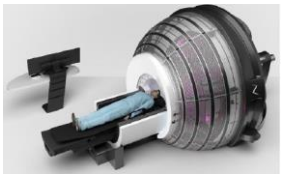
Feature	**Subject Device** Zap-X Radiosurgery System	**Primary Predicate Device** Zap-X Radiosurgery System (K183698)	**Reference Device** Cyberknife M6 Systems (K150873)	Analysis of Differences
Product Image				None
Service Life	Identical to the primary predicate device	With proper care and maintenance, the expected service life of the system is 10 years.	With proper care and maintenance, the expected operating life of the system is 10 years.	None
Side Effects	Identical to the primary predicate device and reference device.	Mild and temporary, often involving fatigue, nausea, and skin irritation. Side effects can be severe, leading to pain, alterations in normal body functions (for example, salivary function), deterioration of quality of life, permanent injury, and even death.	Mild and temporary, often involving fatigue, nausea, and skin irritation. Side effects can be severe, leading to pain, alterations in normal body functions (for example, salivary function), deterioration of quality of life, permanent injury, and even death.	None

510(K) SUMMARY

Feature	**Subject Device** Zap-X Radiosurgery System	**Primary Predicate Device** Zap-X Radiosurgery System (K183698)	**Reference Device** Cyberknife M6 Systems (K150873)	Analysis of Differences
Product Image				None
Occurrence of Side Effects	Identical to the primary predicate device and reference device.	During or shortly after radiation treatment or in the months and years following radiation.	During or shortly after radiation treatment or in the months and years following radiation.	None
Treatment Site	Identical to the primary predicate device	Brain, head, and neck	Brain, head, and neck, all other anatomical regions in the body	Reference device treats entire body while subject and predicate devices treat head, neck and brain only
Accelerator (treatment beam)	Identical to the primary predicate device	3MV nominal photon beam energy	6 MV nominal photon beam energy	Higher energy required for reference device to treat other anatomical locations deeper in the body
Dose rate (in MU/min)	Identical to the primary predicate device	1500±10% MU/min at 450 mm	1000±10% MU/min at 800 mm	None
Depth at Maximum Dose (Dmax)	Identical to the primary predicate device	7±1 mm	15±2 mm	None

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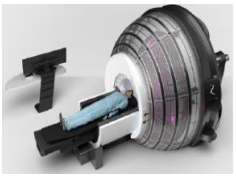
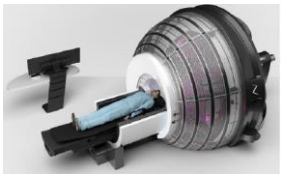
Feature	**Subject Device** Zap-X Radiosurgery System	**Primary Predicate Device** Zap-X Radiosurgery System (K183698)	**Reference Device** Cyberknife M6 Systems (K150873)	Analysis of Differences
Product Image				None
Treatment Beam	Identical to the primary predicate device	8 available beam sizes: diameters 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 the Source to Axis distance of 450 mm	5, 7.5, 10, 12.5, 15, 20, 25, 30, 35, 40, 50 and 60 mm diameter field sizes at 800 mm SAD (with Iris Aperture Collimator)	None
Moveable Treatment Beam	Identical to the primary predicate device	Yes – Two degree of freedom gantry	Yes – Six degree of freedom robotic arm	None
Patient Table/Couch	Identical to the primary predicate device	Yes	Yes	None
Treatment Table	Identical to the primary predicate device	Movable table with 3 degrees of freedom	Moveable table with 5 degrees of freedom	None
Number of Treatment sessions	Identical to the primary predicate device	Single or a short course of hypofractionation (2-5 sessions) for larger lesions (>3 cm)	Single or a short course of hypofractionation (2-5 sessions) for larger lesions (>3 cm)	None
Overall treatment duration	Identical to the primary predicate device device	1-2 weeks	1-2 weeks	None
Treatment Beam Technology	Identical to the primary predicate device	Linac system	Linac System	None

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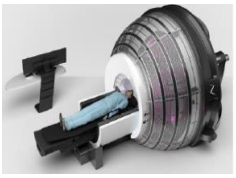
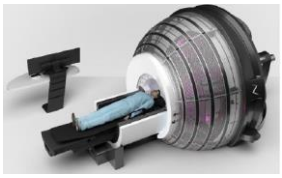
Feature	**Subject Device** Zap-X Radiosurgery System	**Primary Predicate Device** Zap-X Radiosurgery System (K183698)	**Reference Device** Cyberknife M6 Systems (K150873)	Analysis of Differences
Product Image				None
Photon Radiation Source	Identical to the primary predicate device	X-ray Photons	X-ray Photons	None
Beam Crossfire	Identical to the primary predicate device	Non-coplanar	Non-coplanar	None
Shielding for ionizing radiation	Identical to the primary predicate device	Self-shielded	Treatment Vault	None
Treatment Beam Energy	Identical to the primary predicate device	3 MeV nominal photon beam energy (1.0MeV mean photon energy)	6 MeV nominal photon beam energy (2.0MeV mean photon energy)	None
Dose Rate	Identical to the primary predicate device	1500±10% MU/min at 450mm	1000±10% MU/min at 800 mm	None
Real-Time Dosimetry	Identical to the primary predicate device	Yes	Yes	None
Safety subsystem	Identical to the primary predicate device	Yes	Yes	None
System console (operating panel) and user interface software	Identical to the primary predicate device	Yes	Yes	None

SECTION 5.
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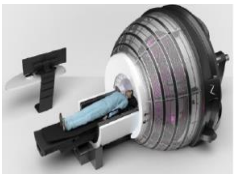
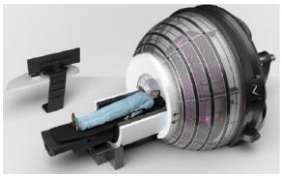
Feature	**Subject Device** Zap-X Radiosurgery System	**Primary Predicate Device** Zap-X Radiosurgery System (K183698)	**Reference Device** Cyberknife M6 Systems (K150873)	Analysis of Differences
Product Image				None
Treatment target tracking software	Identical to the primary predicate device	Yes	Yes	None
Treatment planning software	Identical to the primary predicate device with the added feature: 1.Enhancement made to the patient alignment during treatment.	Yes	Yes	Same as the predicate device except for one new feature
Treatment delivery software	Identical to the primary predicate device	Yes	Yes	None
Method	Identical to the primary predicate device	6D skeletal Tracking System using planar Cranial Imaging and algorithmic comparison real-time bony anatomy with DRRs, at the initiation of and during patient treatment	6D skeletal Tracking System using planar Cranial Imaging and algorithmic comparison real-time bony anatomy with DRRs, at the initiation of and during patient treatment	None
Control	Identical to the primary predicate device	Treatment Console Pendant	Remote Workstation Local Hand Pendant	None

SECTION 5.
510(K) SUMMARY

PERFORMANCE DATA [807.92(b)]

Zap Surgical Systems has performed bench testing to ensure that the modified Zap-X Radiosurgery System performs as intended.

There was one new feature added to the Zap-X System, which is described in the Device Description. That new feature is an improvement in the patient alignment during treatment. Internal testing performed confirmed that the modified Zap-X System meets all design specifications.

This submission also includes a number of less significant changes - primarily bug fixes and also minor enhancements to address user requests and minor technical enhancements. Those changes have also been validated following internal design validation procedures.

NONCLINICAL TESTING SUMMARY [807.92(b)(1)]

The non-clinical bench testing included:

- Electrical safety and electromagnetic compatibility testing
- Software verification and validation testing
- System and subsystem verification testing
- System validation testing of system commissioning, treatment planning, and treatment delivery
- Usability testing
- Standards conformance testing related to radiotherapy systems and radiographic equipment

The standards used in the development and testing of the Zap-X System include the following:

- IEC 60601-1:2012, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC60601-1-2:2014 Electromagnetic disturbances - Requirements and tests
- IEC60601-2-1:2014 Basic safety and essential performance of linear accelerators in the range of 1 MeV to 50 MeV
- IEC60825-1:2014 Safety of laser products - Part 1: Equipment classification and requirements
- IEC61217:2011 Radiotherapy equipment - Coordinates, movements, and scales
- IEC62083:2009 Medical electrical equipment - Requirements for the safety of radiotherapy treatment planning systems
- IEC60976:2007 Medical electrical equipment - Medical electron accelerators - Functional performance characteristics
- IEC62304:2015 Medical device software - Software life-cycle processes
- IEC62366:2015 Medical devices - Application of usability engineering to medical devices

SECTION 5.
510(K) SUMMARY

The collective results of the nonclinical testing demonstrate that the design, manufacturing, and commissioning processes, safety controls, treatment planning, and treatment delivery of the modified Zap-X Radiosurgery System meet the established specifications necessary for consistent performance during its intended use. In addition, the collective bench testing demonstrates that the subject device is substantially equivalent to the predicate device.

SECTION 5.
510(K) SUMMARY

CLINICAL TESTING SUMMARY [807.92(b)(2)]

This section is not applicable. No clinical testing was performed to support this premarket notification.

CONCLUSIONS [807.92(b)(3)]

Extensive nonclinical safety and performance testing have been performed on the subject device to evaluate the device's overall performance. The collective results confirm that the subject device is substantially equivalent to the predicate device. The subject device meets its specifications, exhibits the required mechanical and functional characteristics for its intended use, and demonstrates that it is substantially equivalent to the legally marketed predicate device.

The subject device was compared to the predicate device with respect to product labeling, intended use, anatomical sites, patient population, performance testing, technological characteristics, and safety characteristics. Based on this comparison, there were only minor differences in the technological characteristics between the devices. In addition, the modified Zap-X System is similar to the reference device with regard to indications for use, and other system features. By virtue of the above analysis, the subject device is substantially equivalent to the primary predicate as well as the reference device.

SUMMARY

The Zap-X Radiosurgery System is considered substantially equivalent to the predicate device.