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

February 25, 2019

Re: K183698
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: December 27, 2018
Received: December 31, 2018

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael D. O'Hara 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)*

K183698

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) Notification K183698

GENERAL INFORMATION [807.92(a)(1)]

Applicant:

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Contact Person:

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Date Prepared: December 21, 2018

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

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

Zap Surgical Systems, Inc. asserts that the modified Zap-X Radiosurgery System ("Zap-X System") is substantially equivalent to the predicate device, Zap-X Radiosurgery System, cleared under 510(k) K171804. The modified Zap-X System and the predicate device are medical charged-particle radiation therapy systems, falling within 21 CFR 892.5050, Product Code IYE. The proposed modified Zap-X Radiosurgery System 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 modified Zap-X System is also appropriately comparable to Accuray Cyberknife M6 System (reference device) cleared under 510(k) 150873.

DEVICE DESCRIPTION [807.92(a)(4)]

The modified Zap-X Radiosurgery System ("Zap-X 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 source of therapeutic radiation and a kV imaging system is used to accurately locate the treatment target. At the start of treatment, X-ray images of 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.

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

The modified 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.

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

With regard to technological characteristics, the modified Zap-X Radiosurgery System, originally cleared Zap-X device and reference device all have similar features and components. All three systems utilize a Linac system to generate the treatment beam.

The proposed device, as well as the predicate and reference devices all use a collimator to control the treatment beam size. The treatment beam sizes offered with the modified Zap-X System are identical to the predicate device and within the ranges offered by the reference 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 proposed device, predicate device and reference device Accuray CyberKnife all have an imaging system to accurately deliver radiation to the treatment target. All systems have control consoles and interface software to control and monitor the systems for treatment planning and treatment delivery. All systems include capabilities for patient tracking. The modified Zap-X System, like the primary predicate and CyberKnife, use 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 and electromagnetic compatibility per the relevant standards for medical electrical equipment, electron accelerators and radiotherapy equipment.

The primary difference in technological features between the predicate Zap-X System and the modified Zap-X System is that the latter has implemented a number of minor design changes. The modified Zap-X System is identical to the original Zap-X device with respect to design in that both systems are intended to treat lesions of the head. Finally, the modified Zap-X System 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 original Zap-X System as well as the reference CyberKnife device within a radiation shielded vault.

SUBSTANTIAL EQUIVALENCE

With regard to a primary predicate device, the modified Zap-X System is identical to the original Zap-X System cleared on September 21, 2017 (K171804). Both devices share the same general intended use, i.e., the planning and performance of image guided stereotactic radiosurgery and precision radiotherapy. In addition, the proposed brain, head and neck targets to be treated by the modified Zap-X System are identical to the treatment targets of the originally cleared Zap-X System and are a subset of 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.

Substantial Equivalence Table

Table 12.1. Substantial Equivalence Table

Feature	**Proposed Device** Zap-X Radiosurgery System	**Primary Predicate Device** Zap-X Radiosurgery System (K171804)	**Reference Device** CyberKnife M6 Systems (K150873)	Analysis of Differences
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	Same as 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.	None
Accelerator (treatment beam)	Same as primary predicate device	3MV nominal photon beam energy	6 MV nominal photon beam energy	None
Dose rate (in MU/min)	Same as primary predicate device	1500±10% MU/min at 450 mm	1000±10% MU/min at 800 mm	None
Depth at Maximum Dose (Dmax)	Same as primary predicate device	7±1 mm	15±2 mm	None
Treatment Beam	Same as 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	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	None

Feature	**Proposed Device** Zap-X Radiosurgery System	**Primary Predicate Device** Zap-X Radiosurgery System (K171804)	**Reference Device** CyberKnife M6 Systems (K150873)	Analysis of Differences
		of 450 mm	Collimator)	
Moveable Treatment Beam	Same as primary predicate device	Yes – Two degree of freedom gantry	Yes – Six degree of freedom robotic arm	None
Patient Table/Couch	Same as primary predicate device	Yes	Yes	None
Shielding for ionizing radiation	Same as primary predicate device	Self-shielded	Treatment Vault	None
Real-Time Dosimetry	Same as primary predicate device	Yes	Yes	None
Safety subsystem	Same as primary predicate device	Yes	Yes	None
System console (operating panel) and user interface software	Same as primary predicate device	Yes	Yes	None
Treatment target tracking software	Same as primary predicate device	Yes	Yes	None
Treatment planning software	Same as primary predicate device with addition of two features: 1. Allow user to select pre-generated dose volume for treatment 2. Optimize user workflow of multiple metastatic tumors	Yes	Yes	Same as predicate with the exception of two new features

Feature	**Proposed Device** Zap-X Radiosurgery System	**Primary Predicate Device** Zap-X Radiosurgery System (K171804)	**Reference Device** CyberKnife M6 Systems (K150873)	Analysis of Differences
Treatment delivery software	Same as primary predicate device	Yes	Yes	None

PERFORMANCE DATA [807.92(b)]

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

[807.92(b)(1)] Nonclinical Testing Summary:

The nonclinical, 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 60601-1:2005, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

- IEC 60601-1-2: 2007, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
- IEC 60601-2-1:2014, Medical electrical equipment - Part 2-1: Requirements for the basic safety and essential performance of electron accelerators in the range 1 MeV to 50 MeV
- IEC 60825-1, 2014: Safety of laser products Part 1: Equipment classification and requirements
- IEC 61217, 2011-12: Radiotherapy equipment - Coordinates, movements and scales
- IEC 62083, 2009-09: Medical electrical equipment - Requirements for the safety of radiotherapy treatment planning systems

The collective results of the nonclinical testing demonstrate that the design, the 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 modified Zap-X Radiosurgery System does not raise different questions of safety or effectiveness for image guided stereotactic radiosurgery and precision radiotherapy when compared to the predicate devices.

[807.92(b)(2)] Clinical Testing Summary:

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 has been performed on the modified Zap-X Radiosurgery System to evaluate the overall performance of the device. The collective results confirm that the modified Zap-X Radiosurgery System is safe and effective, meets its specifications, exhibits the required mechanical and functional characteristics for its intended use and demonstrate that the device is safe, effective and performs as safely and effectively as the legally marketed predicate device.

The proposed Zap-X Radiosurgery System 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 which do not raise any different questions of safety or effectiveness. In addition, the modified Zap-X System is similar to the reference device with regard to treatment energy, indications for use and other system features. By virtue of the above analysis, the modified Zap-X System is considered to be substantially equivalent to the primary predicate device.

SUMMARY

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