



Food and Drug Administration  
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Zap Surgical Systems  
% Ms. Darlene Crockett-Billig,  
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SAN JOSE CA 95110

September 21, 2017

Re: K171804  
Trade/Device Name: Zap-X Radiosurgery System  
Regulation Number: 21 CFR 892.5050  
Regulation Name: Medical charged-particle radiation therapy system  
Regulatory Class: II  
Product Code: IYE  
Dated: June 15, 2017  
Received: June 19, 2017

Dear Ms. Crockett-Billig:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, “Misbranding by reference to premarket notification” (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH’s Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



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

## Indications for Use

510(k) Number (if known)

K171804

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**

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**510(k) Notification K 171804**

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**GENERAL INFORMATION [807.92(a)(1)]**

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**Date Prepared: June 15, 2017**

**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**

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

Zap Surgical Systems, Inc. asserts that the Zap-X Radiosurgery System (“Zap-X System”) is substantially equivalent to the predicate device, Accuray CyberKnife M6 Systems, cleared under 510(k) K150873. The 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 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 Zap-X System is also appropriately comparable to another device (i.e., reference device), the Leksell Gamma Knife Icon (K151561). The Gamma Knife Icon is classified as a radionuclide radiation therapy system per 21 CFR 892.5750, Product Code IWB. This reference device is included as it is similar to the Zap-X System with respect to treatment energy, indications for use and other features.

### **DEVICE DESCRIPTION [807.92(a)(4)]**

The 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 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 Zap-X System tracks patient movement and adjusts the table precisely to compensate for such movement.

### **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.

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

With regard to technological characteristics, the Zap-X Radiosurgery System, predicate device and reference device all have similar features and components. The Zap-X System and the CyberKnife utilize a Linac system to generate the treatment beam. Because the CyberKnife, a whole-body radiosurgery system, operates at a somewhat higher energy compared to the Zap-X System (6MV vs. 3MV, respectively), the Leksell Gamma Knife Icon (K151561) device, manufactured by Elekta Instruments AB, has been included as a reference device. Specifically, the Gamma Knife Icon, the indications for which include the treatment of head structures, operates at an energy of 1.17MV and 1.33MV by virtue of its <sup>60</sup>Cobalt irradiation sources. The energy of these photon beams is quite comparable to the average 1MV photons produced by the Zap-X System 3MV Linac.

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 Zap-X System are within the ranges offered by the CyberKnife, as well as the Gamma Knife reference device. Moreover, all three systems deliver treatment beam 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 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 Zap-X System, like the CyberKnife, uses patient skeletal anatomy to align the treatment target with respect to the system isocenter. As with the CyberKnife, the Zap-X System uses the kV imaging system to track patient movement and adjust the table precisely to compensate for such movement during treatment. The Zap-X System, like the predicate and references devices, was 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 CyberKnife and the Zap-X System is that the latter is more compact and self-shielded, enabling it to be installed and used in a standard healthcare facility without a specialized shielded vault. The Zap-X System is comparable to the Gamma Knife Icon reference device with respect to design in that both systems are intended to treat lesions of the head. Although the Gamma Knife Icon does include some self-shielding that limits radiation exposure outside the treatment device, a specialized treatment vault is still required to protect both system operators and general public. Finally, the Zap-X System was demonstrated to meet the requirements for radiation leakage and provide protection from radiation to the operator and general public similar to that of CyberKnife within a radiation shielded vault.

#### **SUBSTANTIAL EQUIVALENCE**

With regard to a primary predicate device, the Zap-X System is most like the CyberKnife M6 System (K150873) manufactured by Accuray. 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 Zap-X System are inclusive within the CyberKnife's indications for use, i.e., "for treatment of lesions, tumors and conditions anywhere in the body". Furthermore, the CyberKnife and Zap-X System have comparable major system components. A minor difference in the energy of the treatment beam (6MV vs. 3MV) does not raise any new issues in terms of either the safety or effectiveness of treatment.

The Zap-X System is also appropriately comparable to another device (i.e., reference device), the Leksell Gamma Knife Icon (K151561) manufactured by Elekta Instruments AB. Notably, the intended use of the Gamma Knife for "stereotactic irradiation of structures in the head" closely matches that being proposed for the Zap-X System. Moreover, a heavily shielded design intended to minimize the extent of ionizing radiation leakage, albeit to differing extents, results in both the Gamma Knife and Zap-X System sharing a rather similar shape. Finally, the energy of the ionizing radiation beams generated by the Gamma Knife's radionuclide Cobalt is quite similar to the average energy produced by the Zap-X System.

Detailed comparisons of the proposed Zap-X Radiosurgery System to the CyberKnife predicate device and Gamma Knife Icon reference device are provided in the following table.

**510(k) SUMMARY**

**Substantial Equivalence Table**

<b>Feature</b>	<b>Proposed Device Zap-X Radiosurgery System</b>	<b>Primary Predicate Device CyberKnife M6 Systems (K150873)</b>	<b>Reference Device Gamma Knife Icon (K151561)</b>	<b>Analysis of Differences</b>
Regulation Number	21 CFR 892.5050 Medical charged-particle radiation therapy system	21 CFR 892.5050 Medical charged-particle radiation therapy system	21 CFR 892.5750 Radionuclide radiation therapy system	Broadly all three devices fall within the general category of radiotherapy systems.
Classification Product Code	IYE	IYE	IWB	--
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.	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.	Leksell Gamma Knife® Icon™ is a teletherapy device intended for stereotactic irradiation of head structures ranging from very small target sizes of a few millimeters to several centimeters, e.g. metastatic tumors, arteriovenous malformations, trigeminal neuralgia, medically refractory essential tremor, meningiomas, vestibular schwannomas, post-surgical pituitary adenomas and recurrent glioblastomas.	Zap-X System Indications falls within broad indication of CyberKnife and has same intended use as the Gamma Knife Icon for treatment of lesions in the head.
Accelerator (treatment beam)	3MV nominal photon beam energy	6 MV nominal photon beam energy	Not Applicable. Irradiation Source is <sup>60</sup> Cobalt with emission at 1.17 and 1.33MV	Energy level of Zap-X falls within range of CyberKnife and Gamma Knife Icon.

**510(k) SUMMARY**

<b>Feature</b>	<b>Proposed Device Zap-X Radiosurgery System</b>	<b>Primary Predicate Device CyberKnife M6 Systems (K150873)</b>	<b>Reference Device Gamma Knife Icon (K151561)</b>	<b>Analysis of Differences</b>
Dose rate (in MU/min)	1500±10% MU/min at 450 mm	1000±10% MU/min at 800 mm	300 cGy/min (in comparing isotopes to Linacs: 1 cGy~1MU)	Zap-X System dose rate is similar to the CyberKnife.
Depth of Dose Maximum (Dmax)	7 ±1 mm	15±2 mm	~5 mm	Depth at maximum dose for Zap-X System is very comparable to Gamma Knife Icon which is appropriate, given its similar intended use.
Treatment Beam	8 available beam sizes: diameters of 4.0, 5.0, 7.5, 10.0, 12.5, 15.0, 20.0 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)	System uses 3 different sets of fixed collimator apertures (4 mm, 8mm and 16 mm)	Zap-X System treatment beam sizes fall within available sizes of the predicate and reference devices.
Moveable Treatment Beam	Yes – Two degree of freedom gantry	Yes – 6 degree of freedom robotic arm	No - 192 <sup>60</sup> Co source arranged in ‘hemisphere’ to treat intracranial lesions	All systems deliver treatment beam from a variety of directions.
Patient Table/Couch	Yes	Yes	Yes	All systems have a patient table or couch to support patient during treatment.
Shielding for ionizing radiation	Self-shielded	Treatment Vault	Partial Self-shielding and Treatment Vault	All three systems protect the operator and the general public from the radiation from the machine.
Real-Time Dosimetry	Yes	Yes	No	Like the predicate, the Zap-X System includes real-time dosimetry.

**510(k) SUMMARY**

<b>Feature</b>	<b>Proposed Device Zap-X Radiosurgery System</b>	<b>Primary Predicate Device CyberKnife M6 Systems (K150873)</b>	<b>Reference Device Gamma Knife Icon (K151561)</b>	<b>Analysis of Differences</b>
Safety subsystem	Yes	Yes	Yes	All systems provide safety control subsystems.
System console (operating panel) and user interface software	Yes	Yes	Yes	All systems provide control consoles.
Treatment target tracking software	Yes	Yes	Yes	All systems allow for patient tracking during therapy.
Treatment planning software	Yes	Yes	Yes	All systems include treatment planning software.
Treatment delivery software	Yes	Yes	Yes	All systems provide treatment delivery software.

**PERFORMANCE DATA [807.92(b)]**

Zap Surgical Systems has performed bench testing to ensure that the 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

## 510(k) SUMMARY

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- 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 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 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 Zap-X Radiosurgery System to evaluate the overall performance of the device. The collective results confirm that the 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 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 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.