DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

September 27, 2016

Aktina Medical Corporation
% Mr. Tony Spaccarotella
Director, Quality Assurance/Regulatory Affairs
360 North Route 9W
CONGERS NY 10920

Re: K161984
Trade/Device Name: Circular Small Field Collimators, Elekta Integrated
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: July 18, 2016
Received: July 19, 2016

Dear Mr. Spaccarotella:

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,

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)*
K161984

Device Name

Circular Small Field Collimators, Elekta Integrated

Indications for Use *(Describe)*

The Circular Small Field Collimators, Elekta Integrated, are intended for use with the Elekta line of digital medical linear accelerators (LINAC) for the creation of small circular fields. These fields are used for patients who require external beam radiation therapy or stereotactic radiosurgery of the cranial or extra cranial regions for the treatment of tumors or lesions.

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.

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510(k) Summary

In Compliance with 21 CFR Section 807.92(c)

1. General Provisions

Device Trade Name:	Circular Small Field Collimators, Elekta Integrated
Common Name:	Circular Small Field Collimators
Owner Name and Address:	Aktina Medical Corporation 360 North Route 9 W Congers, New York, 10920 Phone: 845-268-0101 Fax: 845-268-1700 Registration Number: 2436865

2. Contact Person: Tony Spaccarotella, Director, QA/RA

3. Date Prepared: July 18, 2016

4. Classification

This device is classified as a class II device according to 21 CFR 892.5050, "Medical charged-particle radiation therapy system." The product code is IYE.

5. Predicate Device

Integrated Conical Collimator Verification and Interlock system (ICVI), 510(k) No. K123788, Varian Medical Systems, 3100 Hansen Way, Palo Alto, CA 94304 USA

6. Description

This is a Traditional 510(k) that describes the Circular Small Field Collimators, Elekta Integrated, 50-370, a tertiary collimation system used in conjunction with digital medical linear accelerators (LINAC) for external beam radiation therapy. It consists of collimator cone inserts and a cone insert mounting adapter. The collimator cone inserts create small circular fields of various sizes. Each cone insert is uniquely identified with the diameter in millimeters on the top and bottom covers. The cone mounting adapter is inserted directly into the beam block tray slot of the LINAC head without any need for modification to the LINAC. The collimator cones are easily inserted into and removed from the mounting adapter without removing the adapter from the LINAC. The collimator cone inserts are also uniquely identified electronically, and use the LINAC beam block tray electronic interlock to prevent irradiation, if the cone insert size does not conform to the treatment plan.

7. Intended Use

The Circular Small Field Collimators, Elekta Integrated, are intended for use with the Elekta line of digital medical linear accelerators (LINAC) for the creation of small circular fields. These fields are used for patients who require external beam radiation therapy or stereotactic radiosurgery of the cranial or extra cranial regions for the treatment of tumors or lesions.

8. Technological Characteristics

The Table below compares the technological characteristics of the Aktina Circular Small Field Collimators to the Predicate Device:

Item	**Predicate Device, K123788** **Integrated Conical Collimator Verification and Interlock system (ICVI)** **Varian Medical Systems**	**This 510(k) Submission** **Aktina Circular Small Field Collimators, Elekta Integrated, 50-370** **Aktina Medical Corp.**	**Equivalent or Better for Intended Use?**
1.	**Design:** For compatible Linear Accelerators (LINAC) for attenuation of the beam to create small circular fields.	**Design:** For compatible Linear Accelerators (LINAC) for attenuation of the beam to create small circular fields.	Equivalent
2.	**Components:** Mounting Adapter and Conical Collimators (7 sizes, 2.5 mm increments)	**Components:** Mounting Adapter and Conical Collimators (37 sizes, 1 mm increments)	Better
3.	**Technology:** a. Tertiary small field circular collimation b. Mechanical mounting interface at LINAC c. Automated, electronic collimator cone size detection and interlock control. d. LINAC jaws are electronically verified.	**Technology:** a. Tertiary small field circular collimation b. Mechanical mounting interface at LINAC c. Automated, electronic collimator cone size detection and interlock control. d. LINAC jaws are electronically verified.	a. Equivalent b. Equivalent c. Equivalent d. Equivalent
4.	**Materials:** a. **Mounting Adapter Materials:** Aluminum, Stainless Steel, Brass, Copper, PCB, Cabling b. **Collimator Cone Insert Materials:** Tungsten and Aluminum	**Materials:** a. **Mounting Adapter Materials:** Aluminum, Stainless Steel, Brass, Copper, PCB, Cabling b. **Conical Collimator Materials:** Lead and Stainless Steel	a. Equivalent b. Equivalent
5.	**Biocompatibility:** Not applicable. No patient contact.	**Biocompatibility:** Not applicable. No patient contact.	Not applicable
6.	**Sterility:** Non-sterile.	**Sterility:** Non-sterile.	Not applicable
7.	**Compatibility with Environment** Environment during use is a linear accelerator suite in the radiation therapy	**Compatibility with Environment** Environment during use is a linear accelerator suite in the radiation therapy	Equivalent

	department of a hospital or similar environment.	department of a hospital or similar environment.	
8.	**Compatibility with Other Devices** Does not attach or electrically connect to any other devices except the linear accelerators described in the manufacturer's labeling.	**Compatibility with Other Devices** Does not attach or electrically connect to any other devices except the linear accelerators described in the manufacturer's labeling.	Equivalent
9.	**Electrical / Mechanical / Radiation Safety** Compliant with applicable IEC safety, usability and performance standards and ISO 14971 Risk management Standard.	**Electrical / Mechanical / Radiation Safety** Compliant with applicable IEC safety, usability and performance standards and ISO 14971 Risk management Standard.	Equivalent
10.	**Chemical / Thermal Safety** Not applicable. The device does not generate or contain hazardous chemicals or thermal energy.	**Chemical / Thermal Safety** Not applicable. The device does not generate or contain hazardous chemicals or thermal energy.	Equivalent

9. Performance Standards and Data

The FDA under Section 514 of the Food, Drug and Cosmetic Act has not established performance standards for this product

Hardware specification testing has been performed for this device to show that the verification, validation and safety requirements have been met regarding:

- All specified functional, performance, safety and labeling requirements,
- Use and performance with the linear accelerators and accessories specified,
- Assessment against ISO 14971 Risk Management requirements,
- Assessment against applicable sections of these IEC Standards: 60601-1, Medical Electrical Equipment, General requirements for basic safety and essential performance; 60601-2-1, Basic safety and essential performance of electron accelerators in the range 1 Mev to 50 Mev; 62366-1, Application of usability engineering to medical devices.

This device does not contain software.

The testing has demonstrated substantial equivalence or better when compared to the predicate device.

10. Biocompatibility

Not applicable. There are no patient contact components.

11. Summary of Substantial Equivalence

The Circular Small Field Collimators, Elekta Integrated, 50-370, is at least substantially equivalent to the predicate device in design, intended use, and all other technological, physical, safety, compatibility, and performance characteristics. The testing results have demonstrated that the device performs as well as or better than the predicate device. No new issues of safety or effectiveness are introduced by using this device. Therefore, Aktina Medical Corp. believes that the Circular Small Field Collimators, Elekta Integrated, 50-370, is substantially equivalent to the predicate device.