ELEKTA

K112613

DEC 16 2011

510(k) SUMMARY

Date of preparation of summary: 1st September 2011

Submitted by:

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Contact name: Mr. Andrew Hedges

Trade Name: Integrity™ R1.1

Common Name: Control System, Medical Linear Accelerator

Classification Name: Medical charged-particle radiation therapy system, 21CFR 892.5050

Product Code: IYE

Predicate Device: Integrity™ R1.0 (K102200)

Product Description:

This Traditional 510(k) describes enhancements to the integral software performing the interface and machine control functions for the Elekta Limited range of medical digital linear accelerators. These modifications provide improvements to beam delivery, compatibility with a wider range of Elekta products and the provision of diagnostic tools to assist service engineers

Intended Use Statement:

Integrity™ is the interface for the Elekta range of digital medical linear accelerators and is intended to assist a licensed practitioner in the delivery of radiation to defined target volumes (e.g. lesions, arterio-venous malformations, malignant and benign tumours), whilst sparing surrounding normal tissue and critical organs from excess radiation. It is intended to be used for single or multiple fractions, delivered as static and/or dynamic beams of radiation, in all areas of the body where such treatment is indicated.

Summary of Technological Characteristics:

Integrity™ is an integrated digital control system, providing interface and machine control functions for the Elekta Limited range of digital accelerators. It comprises a dedicated control cabinet on which the interface and machine control software is executed. There has been no change made to the underlying technological characteristics of the product from the predicate device.

Substantial Equivalence

The functionality for Integrity™ is substantially equivalent to its predicate device, Integrity™ R1.0 (K102200) in safety and effectiveness. The intended use, principles of operation, technological characteristics and labelling are the same or equivalent to the predicate device.

The primary difference between the predicate device and the modified device is the improved consistency of VMAT beam delivery and added flexibility for fault diagnosis. It does not introduce additional clinical functionality or performance.

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Functionality	NEW DEVICE Integrity R1.1		PREDICATE DEVICE IntegrityR1.0	
	MLCi2	BM	MLCi2	BM
MLC move during irradiation	No change		YES	YES
Max. speed of MLC movement	No change		2cm/s	2.5cm/s
Variable leaf speed	No change		YES	YES
Interdigitation	No change		YES	YES
Back up diaphragms	No change		YES	NO
Back up diaphragms move during irradiation	No change		Track last leaf for lower leakage	N/A
Gantry move during irradiation	No change		YES	YES
Variable gantry speed	No change		YES	YES
Collimator rotates during irradiation	No change		YES	YES
Variable Doserates (available dose rates)	No change		YES (255)	YES (255)
Treatment Delivery Time ≈	No change		1.4 min	1.4 min

Summary of non clinical performance testing

Testing in the form of module, integration and system level verification was performed to evaluate the performance and functionality of the new and existing features against the requirement specification.
Regression testing has been performed successfully to verify the integrity of any changes.

Validation of the system under actual use conditions have been performed by competent and professionally qualified personnel. Results from verification and validation testing demonstrate that conformance to applicable technical design specification and assured safety & effectiveness have been met.

Testing has been undertaken on both production equivalent systems at Elekta and at customer sites.

The system is subject to compliance testing to voluntary consensus safety standards. Details of the standards employed in the design are specified in the Standard Data Report in section 9 which includes but not limited to IEC 60601-1, IEC 60601-2-1, IEC 60601-1-4, IEC 62304, IEC 60601-1-6, IEC 62366 and ISO 14971.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Mr. Andrew Hedges
Regulatory Affairs Engineer
Elekta Limited
Linac House
Crawley, West Sussex RH10 9RR
UNITED KINGDOM

DEC 16 2011

Re: K112613
Trade/Device Name: Integrity R1.1
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: November 7, 2011
Received: November 9, 2011

Dear Mr. Hedges:

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.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. 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 Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S Pastel

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K112613

Device Name: Integrity R1.1

Indications for Use: Integrity™ is the interface and control software for the Elekta range of medical digital linear accelerators and is intended to assist a licensed practitioner in the delivery of radiation to defined target volumes (e.g. lesions, arterio-venous malformations, malignant and benign tumours), whilst sparing surrounding normal tissue and critical organs from excess radiation. It is intended to be used for single or multiple fractions, delivered as static and/or dynamic beams of radiation, in all areas of the body where such treatment is indicated

Prescription Use _____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

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