ELEKTA

K102200

510(k) SUMMARY

NOV - 4 2010

Date of preparation of summary: 28th July 2010

Submitted by:
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Contact name: Mr. Andrew Hedges

Trade Name:	Integrity™ R1.0
Common Name:	Control System, Medical Linear Accelerator
Classification Name:	Medical Linear Accelerator Accessory, IYE
Predicate Device:	Desktop Pro™ (K080585)

Product Description:

This Traditional 510(k) describes enhancements to the integral software performing the graphical interface and machine control functions for the Elekta range of medical digital linear accelerators. Integrity R1.0 employs a new LynxOS operating system that has a proven track record in safety and security to replace RMX. The software introduces Continuously Variable Dose Rate (CVDR), which is an enhancement to standard dose rate for dynamic delivery techniques. This function increases the number of available dose rates which can make treatment delivery more efficient and provide smoother delivery of VMAT prescriptions. The software supports the ability for the MLCi2 leaves to interdigitate, supporting the creation of island fields for X-Ray treatment delivery techniques.

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 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 equivalent to its predicate device the Elekta Desktop Pro™ (K080585) in safety and effectiveness. The fundamental technical characteristics are the same as those of the predicate device and differences in operation are described in the comparison chart and discussion provided elsewhere in this 510(k) submission.

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, Fleming Way
Crawley, West Sussex RH10 9RR
UNITED KINGDOM

NOV - 4 2010

Re: K102200
Trade Name: Integrity
Regulation Number: 21 CFR §892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: August 2, 2010
Received: August 4, 2010

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,

David G. Brown, Ph.D.
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

K102200

Indications for Use

NOV - 4 2010

510(k) Number (if known): K102200

Device Name:

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

510K K102200

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