ELEKTA
ONCOLOGY

K100115

510(k) SUMMARY

Date of preparation of summary: January 11th 2010

MAR 10 2010

Submitted by:
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Contact name: Mr Andrew Hedges

Trade Name: XVI R4.5

Common Name: Elekta X-Ray Volume Imaging system, XVI

Classification Name: Medical Linear Accelerator Accessory, 21 CFR 892.5050, IYE

Predicate Device: Elekta Synergy® (K051932)

Product Description:

This Traditional 510(k) describes modifications made to the XVI kilo-voltage imaging accessory of the Elekta range of digital linear accelerators. The primary reason for these enhancements is to improve the acquisition and utilization of kV images in facilitating the correction of patient position for anatomical changes or movement. The additional features are; Symmetry™ (4D VolumeView™) to evaluate respiration induced motion, 3D shaped region of interest for registration, dual registration for quantitative information regarding both the critical structures and target position, and 3D seed registration of implanted markers. Improvements have also been made to the operator interface, connectivity with other systems through DICOM and in the provision of licensable options to tailor individual features.

Intended Use Statement:

The intended use for the device has been amended to incorporate an extended imaging functionality for the confirmation of target localization;

The Elekta X-Ray Volume Imaging system, XVI, is an electronic imaging device (EID), designed to be used with the Elekta range of medical linear accelerators and intended to be used as part of radiation therapy treatment process, as determined by a licensed medical practitioner

XVI, is intended to confirm patient positioning and support decision making in response to target displacement resulting from organ deformation and anatomical movement.
Symmetry™ is a software option within XVI that can be used to acquire and display volumetric images of sequential phases of the breathing cycle for the evaluation of respiration induced motion, to assist in identification of appropriate target locations within anatomical structures in motion.

Summary of Technological Characteristics:

The XVI system consists of a kV radiation source mounted onto the linac gantry drum and a kV radiation image detector. Incorporation of the kV imaging system onto the same structure as the treatment system allows high quality images of the patient anatomy to be acquired at the point of treatment and their content to be spatially related to the forthcoming MV treatment, as previously cleared under Control Number K051932.
There has been no change made to the underlying technological characteristics of the product.

Substantial Equivalence

The functionality for the XVI R4.5 is equivalent to its predicate device XVI R3.5 as part of the Elekta Synergy® (K051932) 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

MAR 10 2010

Re: K100115
Trade/Device Name: XVI
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: January 11, 2010
Received: January 15, 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,

Donald J. St.Pierre
Acting 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): K100115

Device Name: XVI

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Prescription Use __YES__ AND/OR Over-The-Counter Use __NO__
(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 K100115