

510(k) SUMMARY

Date of preparation of summary: June 20th 2013

Submitted by:

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SEP 25 2013

Contact name: Mr Andrew Hedges
Trade Name: XVI R5.0
Common Name: X-Ray Volume Imaging system, XVI
Classification Name: Medical Linear Accelerator Accessory, 21 CFR 892.5050
Product Code: IYE
Predicate Device: Elekta XVI (K100115), Varian TrueBeam (K123291),
Brainlab ExacTrac Vero (K122451)

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 modifications is to further enhance the imaging tools to support the monitoring and management of motion, by allowing visualization of tumor and surrounding critical structures during treatment delivery.

Improvements have also been made to the operator interface connectivity with other systems to support distributed workflow and in the provision of licensable options to tailor individual features.

Intended Use and Indications for use statement:

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 the radiation therapy treatment process for single or multiple fractions, of static and/or dynamic treatments, in gated or un-gated deliveries, in all areas of the body where such image guidance is determined by a licensed physician.

It provides real-time 2D, 3D & 4D image guidance before, during and after treatment delivery, and is intended to support confirmation of patient positioning, monitoring and management of internal motion, and decision making in response to target position, size, shape and displacement resulting from organ deformation and anatomical movement in relation to surrounding critical structures.

XVI facilitates precise and accurate dose placement, and patient set-up correction, through visualization of internal anatomy including target, critical structures and soft tissue with or without the use of implanted markers.

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.

The Elekta digital linear accelerator can be used for treatments that includes but is not limited to malignant and benign brain tumors, brain metastases, spine lesions treated using SRS, squamous cell carcinoma of the head and neck, lung, breast, pancreatic, hepatic malignancies treated using SBRT, prostate, and bone metastases.

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 planned MV treatment, as previously cleared under Control Number (K100115)

There has been no change made to the underlying technological characteristics of the product.

Substantial Equivalence

The release of XVI R5.0 provides the ability to acquire kV images during treatment delivery, expanding the indications for use of its predicate device XVI R4.5 (K100115). The capability for monitoring and managing target motion and patient position during treatment is substantially equivalent to the predicate devices Varian TrueBeam (K123291) and ExacTrac Vero (K122451). Both devices provide localization to assist with patient positioning before, during and after treatment and facilitate patient setup, through visualization of internal anatomy.

The differences in technological characteristics between XVI and the predicate devices do not raise questions of safety and effectiveness.

Functionality	XVI R5.0	XVI R4.5	TrueBeam (Varian)	ExacTrac Vero (BrainLab)
Control Number	K - - - - -	K 100115	K123291	K122451
Visualize bony anatomy on image	No Change	Yes	Yes	Yes
Visualize soft tissue on image	No Change	Yes	Yes	Yes
Visualize implanted markers in patient	No Change	Yes	Yes	Yes
Image patient in treatment position	No Change	Yes	Yes	Yes
2D image acquisition	No Change	Yes	Yes	Yes
Stereoscopic Imaging	Enhanced	Yes	Yes	Yes
3D image acquisition	No Change	Yes	Yes	Yes
4D image acquisition	No Change	Yes	Yes	No
Radiation dose required	Low (kV)	Low (kV)	Low (kV)	Low(kV)
3D Volumetric Registration	No Change	Yes	Yes	Yes
Dual Registration	No Change	Yes	No	No
4D Volumetric Registration	No Change	Yes	Unknown	No
Intra-fraction Imaging	Yes	No	Yes	Yes

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 clinically representative conditions has been performed by competent and professionally qualified personnel. Results from verification and validation testing demonstrate that conformance to applicable technical design specification have been met and safety & effectiveness have been achieved.

Testing has been undertaken on both production equivalent systems at Elekta and at hospital 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 60601-1-3, IEC 60601-2-44, IEC 60601-2-54, IEC 62304, IEC 62366 and ISO 14971.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - W066-G609
Silver Spring, MD 20993-6002

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

September 25, 2013

Re: K131965
Trade/Device Name: XVI R5.0
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: June 20, 2013
Received: June 27, 2013

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. 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.

Page 2—Mr. Hedges

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact 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/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,


for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K131965

Device Name: XVI R5.0

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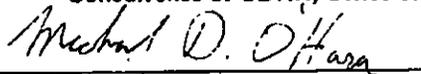
Prescription Use YES
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use NO
(21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

510(k) K131965