



Food and Drug Administration  
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Elekta Limited  
% Mr. Maurice Paine  
Quality & Regulatory Affairs Engineer  
Linac House, Fleming Way  
Crawley, West Sussex RH10 9RR  
UNITED KINGDOM

December 11, 2015

Re: K153011  
Trade/Device Name: iVIEWDose R1.0  
Regulation Number: 21 CFR 892.5050  
Regulation Name: Medical charged-particle radiation therapy system  
Regulatory Class: II  
Product Code: IYE  
Dated: October 9, 2015  
Received: October 14, 2015

Dear Mr. Paine:

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,

A handwritten signature in blue ink that reads "Michael D. O'Hara". The signature is written in a cursive style and is positioned over a faint, large watermark of the FDA logo.

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

## Indications for Use

510(k) Number (if known)  
K153011

Device Name

iViewDose R1.0

Indications for Use (Describe)

iViewDose is a standalone software tool, available as an optional accessory of the linear accelerator. It is intended to assist in reducing the clinical risk in the delivery of radiotherapy treatments and does not alter the treatment delivery, or impact the clinical workflow.

The software is to be used for the purposes of detecting gross errors during the delivery of radiation therapy. The software acquires data using the iViewGT Electronic Portal Imaging Device at the time of treatment (or prior to treatment) and subsequently processes it. The processed data is compared with data calculated by the treatment planning system. The comparison is derived from the application of dose conversion and reconstruction algorithms to the EPID data, which is back-projected to a plane normal to a beam (2D) or multiple planes (3D) inside the patient (in vivo) or phantom (pre-treatment).

iViewDose is not a treatment planning system, and provides an independent means of checking the dose delivered to the patient.

iViewDose therefore provides an added level of treatment assurance, thus giving clinicians greater confidence especially when complex treatment techniques are employed.

iViewDose is intended to support decision making in relation to the delivery of radiation to defined target volumes performed with Elekta linear accelerators only.

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.

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## 510(k) SUMMARY

**Date of preparation of summary:** October 09, 2015  
**Submitted by:** Elekta Limited  
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United Kingdom  
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**Establishment Registration No.:** 9617016  
**Contact Name:** Mr. Maurice Paine  
**Trade Name:** iViewDose R1.0  
**Common Name:** EPID Dosimetry  
**Classification Name:** Medical charged-particle radiation therapy system, 21 CFR 892.5050

**Product Code:** IYE  
**Predicate Devices:** DOSIsoft SA, EPIgray (K112723)  
Math Resolutions LLC, Dosimetry Check Version 4 Release 1 (K132605)  
Math Resolutions LLC, Dosimetry Check with Exit Dose (K101503)

### Product Description:

This Traditional 510(k) describes a new standalone software to be used with the Elekta range of medical linear accelerators, to further enhance the existing functionality.

The iViewDose program uses iViewGT™ images to reconstruct the dose in 3D in the volume (patient or phantom). The program then uses a gamma analysis to compare the reconstructed dose with the TPS dose in 3D. iViewDose uses a dose reconstruction algorithm to calculate the dose in the patient from the dose delivered to the MV detector panel. The algorithm corrects for scattered radiation from the patient and the MV detector panel. You can use iViewDose in vivo to make an estimate of the delivered dose to a patient. You can also use iViewDose for pre-treatment checks to make an estimate of the delivered dose to a phantom.

### Indications for Use and Intended Use statement:

The Intended Use for the iViewDose product is as follows:

iViewDose is a standalone software tool, available as an optional accessory of the linear accelerator. It is intended to assist in reducing the clinical risk in the delivery of radiotherapy treatments and does not alter the treatment delivery, or impact the clinical workflow.

The software is to be used for the purposes of detecting gross errors during the delivery of radiation therapy. The software acquires data using the iViewGT Electronic Portal Imaging

Device at the time of treatment (or prior to treatment) and subsequently processes it. The processed data is compared with data calculated by the treatment planning system. The comparison is derived from the application of dose conversion and reconstruction algorithms to the EPID data, which is back-projected to a plane normal to a beam (2D) or multiple planes (3D) inside the patient (in vivo) or phantom (pre-treatment).

iViewDose is not a treatment planning system, and provides an independent means of checking the dose delivered to the patient.

iViewDose therefore provides an added level of treatment assurance, thus giving clinicians greater confidence especially when complex treatment techniques are employed.

iViewDose is intended to support decision making in relation to the delivery of radiation to defined target volumes performed with Elekta linear accelerators only.

This software does not alter the existing Indications for Use of the Elekta series of medical linear accelerators, and therefore the existing indications for use statement remains valid:

The Elekta medical linear accelerator system is indicated to be used for image guided stereotactic radiosurgery and precision radiotherapy for lesions, tumors, and conditions anywhere in the body when radiation treatment is indicated.

#### **Summary of Technological Characteristics:**

The software utilises MV images taken through the iViewGT™ hardware platform, and calculates the dose delivered at a user specified reference plane in 2D, or multiple planes in 3D. The calculated dose is then compared to the planned treatment dose and provides the clinical user with an indication of whether the dose delivered is in accordance with the planning dose. The software uses a back projection algorithm to product the calculated dose.

There has been no change made to the underlying technological characteristics of the linear accelerator device.

The iViewDose accessory consists of software only, and encompasses several third party software components. These third party components have been treated as SOUP in accordance with IEC62304.

The iViewDose product is subject to compliance testing as defined in internationally recognised safety standards. Details of the standards employed in the design are specified in the Standard Data Report in section 9, whilst the verification activities are captured in section 16-11 of this submission.

#### **Substantial Equivalence:**

The release of iViewDose R1.0 provides the ability to use EPID images acquired from the iViewGT imaging system mounted to a linear accelerator to reconstruct the dose delivered to the patient or phantom. The software compares the reconstructed dose with the planned dose (from a compatible treatment planning system).



The following products are identified as Predicate Devices

- Dosimetry Check with exit Dose from Math Resolutions, LLC (K101503)
- Dosimetry Check Version 4 Release 1 from Math Resolutions, LLC (K132605)
- EPIgray from DOSIsoft SA, (K112723)

Math Resolutions, LLC creates software for use in the radiological sciences. Dosimetry Check has been on the market since 2001.

DOSIsoft was founded in 2002, from a partnership between Gustave Roussy and Institut Curie – two major cancer treatment centres in Europe. EPIgray was launched in 2011 for EPID-based in vivo dosimetry.

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

<b>Functionality</b>	<b>iViewDose R1.0</b>	<b>EPIgray (DOSIsoft SA)</b>	<b>Dosimetry Check Version 4 Release 1 (Math Resolutions, LLC)</b>	<b>Dosimetry Check with Exit Dose (Math Resolutions, LLC)</b>
<b>Control Number</b>	<b>K - - - - -</b>	<b>K112723</b>	<b>K132605</b>	<b>K101503</b>
Independent software	Yes	Yes	Yes	Yes
Option for use with Elekta Radiation Therapy Systems	Yes	Yes	Yes	Yes
Pre-treatment images	Yes	Yes	Yes	Yes
Treatment images	Yes	Yes	Yes	Yes
Algorithm for calculating reconstructed dose	Yes	Yes	Yes	Yes
Compares reconstructed dose to planning system dose	Yes	Yes	Yes	Yes
Generates a report for the reviewer to export to file	Yes	Yes	Yes	Yes
Results include a % difference at the dose reference point	Yes	Yes	Yes	Yes
Volume Analysis per Fraction	Yes	Yes	Yes	Yes
Volume Analysis per Beam	Yes	Yes	Yes	Yes
Total Dose assessment per fraction	Yes	Yes	Yes	Yes
Total Dose assessment per treatment	Yes	Yes	Yes	Yes
Ability to view a Dose profile	Yes	Yes	Yes	Yes
Ability to view EPID images	Yes	Yes	Yes	Unknown
Ability to view analysis in multiple anatomical planes	Yes	Yes	Yes	Yes



Analysis points can be single or multiple (2D or 3D)	Yes	Yes	Yes	Yes
Filters by date, by fraction and by field	Yes	Yes	Yes	Yes
User defined Alert Criteria for out of tolerance analysis	Yes	Yes	Yes	Yes
Import Approved Plan data from Treatment Planning System	Yes	Yes	Yes	Yes
Import portal images acquired during treatment	Yes	Yes	Yes	Yes
Import portal images acquired during pre-treatment	Yes	Yes	Yes	Yes
Analysis performed automatically offline	Yes	Yes	Yes	Yes
Results statistics available in the report	Yes	Yes	Yes	Yes
Results presented as a Gamma Analysis	Yes	Yes	Yes	Yes
Report may be stored within Patient Record in MOSAIQ	Yes	Requires converting to pdf	Requires converting to pdf	Yes
Multiple Treatment Planning Systems  (initially iViewDose is only validated as being compatible with Monaco and Pinnacle)	Yes	Yes	Yes	Yes
MOSAIQ Record & Verify System	Yes	Yes	Yes	Yes
Multiple Treatment techniques  (IMRT and VMAT)	Yes	Yes	Yes	Yes

Multiple EPID's	No	Yes	Yes	Yes
MV Panel Calibration required for commissioning	Yes	Yes	Yes	Yes
Pre-treatment Check	Yes	Yes	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 features against the requirement specification.

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.

This testing has shown that iViewDose is safe in use, as it does not provide any direct clinical functionality. Also, the use of iViewDose has been shown to have equivalent clinical efficacy when compared to the predicate devices for which this submission is claiming.

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 62304, IEC 62366, ISO 14971, and IEC61217.

Although no clinical testing has been performed as part of the development, it can be shown that the algorithm at the core of the iViewDose product has been used extensively for a number of years. The data reviewed as part of this evaluation has been obtained from clinical sites. The data is presented in section 11 of this submission.