DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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December 8, 2016

medPhoton GmbH
% Mr. Daniel Schaffarzick
Official Correspondent
Strubergasse 16
Salzburg, 5020
AUSTRIA

Re: K161400
Trade/Device Name: ImagingRing System
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: November 4, 2016
Received: November 8, 2016

Dear Mr. Schaffarzick:

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,

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161400

Device Name
ImagingRing System

Indications for Use *(Describe)*
The ImagingRing System (IRS) is an X-ray device consisting of (1) imaging components, supports and software and (2) patient support structure (couch top), designed to support patient localization in the Couch Coordinate System (CCS) and intended to be used as image guidance equipment as part of the radiation therapy (RT) treatment process, in all areas of the body where such image guidance is determined by a licensed physician.
IRS facilitates patient localization by means of imaging patient anatomy including the therapeutic target volume, critical structures, bone and soft tissue with or without the use of implanted markers or contrast agents.
IRS provides 2D planar imaging (including streaming and recording sequences of 2D frames for motion analysis) and 3D volumetric imaging before, during and after irradiation, and is intended to support patient positioning, monitoring and management of internal target motion, and decision making as a function of target position, size, shape and displacement resulting from patient set-up deviation, organ deformation and anatomical movement.
With the goal to accurately perform patient alignment with respect to an external treatment beam and to spare critical organs surrounding the target volume, IRS is intended to be:
• embedded in the radiotherapy workflow, i.e. being able to communicate with third party systems used in particle therapy or LINAC based RT such as Oncology Information Systems (OIS) or Radiotherapy Control Systems (RTCS) in order to receive commands and data from and provide information to (e.g., receiving command from RTCS to start an image acquisition and providing image data to RTCS for the purpose to calculate and execute the patient (re)-positioning vector externally in the third party system)
• interfaced with a Patient Positioning Systems (PPS), like - but not limited to - a robotic multi-axis system, to allow the calculated (re)-positioning vector to be applied with respect to Coordinate Systems the treatment delivery unit relates to.

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

In accordance with the requirements of the Safe Medical Device Act, medPhoton GmbH herewith submits a 510(k) Summary.
This 510(k) summary for the ImagingRing System meets the requirements of 21 CFR 807.92.

Date Prepared: November 04th, 2016

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Device(s) Identification:

Device Trade Name:	ImagingRing System
Device common name:	ImagingRing System
Device Classification Name:	Accelarator, Linear, Medical
Regulation Description:	Medical charged-particle radiation therapy system
Product Code:	IYE
Reference:	per 21 CFR 892.5050
Review Panel:	Radiology
Device Class:	II

Device Description:

The medPhoton IRS is a standalone imaging system designed to obtain TwoDimensional (2D) and Three-Dimensional (3D) X-ray images. The images visualize patient's anatomy whose information can be used to accurately position or re-position the patient undergoing radiotherapy treatment.

The IRS consists of

- hardware called ImagingRing (IR) consisting of couch top, ring, detector, X-ray source, generator, etc.;
- software called ImagingRing Software Suite (ImRiSS), to orchestrate image acquisition and data processing;
- programmable logic controller (PLC) components and related software (e.g., ImagingRing Control System - IRCS), to execute and control image acquisition.

The system is designed in a way such that it provides the following key features:

1. During imaging acquisition, the IR can be moved along the couch top in order to acquire images of any anatomical region of interest.
2. The X-ray source and detector can move independently in order to enable nonisocentric acquisition trajectories (i.e., to focus on a selectable center of interest within the patient in an axial plane) and variable size of the axial Field Of View (FOV).
3. The combination of imaging arm and couch top is designed to be directly attached to a range of Patient Positioning Systems (PPS) including multi-axis robotic devices.

The imaging device is integrated with a couch top. The independently moveable components allow for acquisition of X-ray projective images. These provide the foundation for 2D planar imaging as well as acquisition and reconstruction of 3D ConeBeam Computed Tomography (CBCT) images around customizable centers of interest.

Intended Use:

The ImagingRing System (IRS) is an X-ray device consisting of (1) imaging components, supports and software and (2) patient support structure (couch top), designed to support patient localization in the Couch Coordinate System (CCS) and intended to be used as image guidance equipment as part of the radiation therapy (RT) treatment process, in all areas of the body where such image guidance is determined by a licensed physician.

IRS facilitates patient localization by means of imaging patient anatomy including the therapeutic target volume, critical structures, bone and soft tissue with or without the use of implanted markers or contrast agents.

IRS provides 2D planar imaging (including streaming and recording sequences of 2D frames for motion analysis) and 3D volumetric imaging before, during and after irradiation, and is intended to support patient positioning, monitoring and management of internal target motion,

and decision making as a function of target position, size, shape and displacement resulting from patient set-up deviation, organ deformation and anatomical movement.
With the goal to accurately perform patient alignment with respect to an external treatment beam and to spare critical organs surrounding the target volume, IRS is intended to be:

- embedded in the radiotherapy workflow, i.e. being able to communicate with third party systems used in particle therapy or LINAC based RT such as Oncology Information Systems (OIS) or Radiotherapy Control Systems (RTCS) in order to receive commands and data from and provide information to (e.g., receiving command from RTCS to start an image acquisition and providing image data to RTCS for the purpose to calculate and execute the patient (re)-positioning vector externally in the third party system)
- interfaced with a Patient Positioning Systems (PPS), like - but not limited to - a robotic multi-axis system, to allow the calculated (re)-positioning vector to be applied with respect to Coordinate Systems the treatment delivery unit relates to.

Predicate devices:
1. Primary Predicate

Device Trade Name:	XVI R5.0
Applicant:	Elekta Limited
510(k) No.:	K131965

2.

Device Trade Name:	kVue™ IGRT Couch top
Applicant:	Aquaplast/Qfix
510(k) No.:	K060671

The ImagingRing System is considered substantial equivalent to the Elekta XVI R5.0 (K131965) and the kVue™ IGRT Couch top (K060671).

1. Intended use, medical application and treatment method as well as the basic parameter settings are equivalent for the ImagingRing System and the predicate devices.
2. There is no significant difference in intended use or technology.

Summary of Technological Characteristics:

Characteristics	ImagingRing System	XVI R5.0
510(k)	-	K131965
Manufacturer	medPhoton GmbH	Elekta Limited.
Product code	IYE	IYE
Indications for use		
Used with a charged particle or photon radiation therapy system	✓	✓
Verification of patient setup position	✓	✓
Image acquisition		
X-ray imaging with digital flat panel detector	✓	✓
Stereoscopic acquisition	✓	✓
CBCT	✓	✓
Temperature	15°C to 30°C	10°C to 35°C
Humidity	30 to 65 %	30% to 70%
Atmospheric Pressure	80 kPa to 110 kPa	80 kPa to 106 kPa
Motorized movements laterally and longitudinally	✓	✓
Touchguard prevents collision	✓	✓
source just delivers radiation when the source arm is situated in a locked position	-	✓
Touchguard prevents collision	✓	✓
Movements are continuously variable	✓	✓
Beam rotates radially through 360° in the direction of the isocenter	✓	✓
Speed	0 to 1 revolutions/min	0 to 1 revolutions/min
Position Accuracy	±0.2°	±0.3°
Inherent filtration	1.4	1.4
Added filtration	5.2	5.6
Total filtration at 100 kV	6.6	7.0
Nominal voltage	230 V	400 V, 415 V, 440 V, or 480 V
Voltage variation	±10%	±10%
Phases	Single-phase and earth	Three-phase and earth
Frequency	50 – 60 Hz	48 Hz or 62 Hz, ±2%
Impedance	0.2 Ohms	0.348 ohms to 0.501 ohms
Fuse rating	32 A	63 A circuit recommended
confinement of extra focal radiation	extra focal radiation is not more than 15 cm on each side of the largest X-ray field	extra focal radiation is not more than 15 cm on each side of the largest X-ray field
beam limits	Independently moveable X and Y jaws to shape the x-ray field of irradiation	collimator cassettes that you can manually change to set the size of the X-ray beam
leakage radiation in the loading state	0.1979 mGy/h	< 1.0 mGy/h
leakage radiation when not in the loading state	0 mGy/h	< 20 mGy/h
Relation between the X-ray field and image receptor area	At the image receptor plane, the X-ray beam must not be larger than the boundaries by more	At the image receptor plane, the X-ray beam must not be larger than the boundaries by

	than 3% of the source-to-image distance along the two major axes	more than 3% of the source-to-image distance along the two major axes
Radiation warning lamp	✓	✓
80 kV	4.4 mm Al	6.1 mm Al
120 kV	6.3 mm Al	8.5 mm Al
Generator operating range	40 – 120 kVp	70 – 150 kVp[1]
Flat panel detector pixel size	400 µm	400 µm[1]
Flat panel matrix	1024 x 1024	1024 x 1024[1]
2D low contrast visibility	≥12 disks visible	≥12 disks visible[2]
2D spatial resolution	≥1.6 line/mm	≥1.4 line/mm[2]
CBCT spatial resolution	≥10 lp/cm (up to 18)	≥7 lp/cm[1]
CBCT low contrast resolution	< 1.5%	< 1.5%[2]
CBCT uniformity	< 2%	< 2%[2]
Transverse geometric accuracy	< 1 mm	< 1mm[1]
FlexMap[3]	Yes	yes[1]
Presets and automatic setup	The ImagingRing System receives information such as patient and preset selection, from a third party system (e.g. the Radiotherapy Control System of a treatment delivery device) for automatic set up of image acquisition parameters	SYNERGISTIQ[4]
2D planar imaging	✓	PlanarView[5]
Fluoroscopy mode	✓ Recording of frame sequences for motion analysis (pulsed fluoroscopy-like acquisition mode)	MotionView[6]
3D reconstruction	✓	VolumeView[7]
4D volume view	N/A	Symmetry[8]

[1] Data from http://www.aapm.org/meetings/amos2/pdf/34-8077-2750-150.pdf
[2] http://chapter.aapm.org/seaapm/symposia/2015/Weatherford.pdf . Phantom used: Catphan 503.
[3] The term FlexMap indicates a technique to compensate for the deflection of ring mounted components due to the difference in gravitational force along the rotation trajectory, leading to a difference between nominal and actual values as a function of the position in the trajectory.
[4] In SYNERGISTIQ mode, the information from the patient management information system is used to automatically set up the image acquisition parameters, such as patient selection, reference data, and preset selection.
[5] In the PlanarView mode, XVI uses presets to acquire one 2D planar image. The digital accelerator gantry does not move, a sequence of frames is acquired, and XVI does an average of these frames to create the image. The user can acquire images at applicable gantry angles in this mode.
[6] In the MotionView mode, XVI uses presets to acquire a sequence of 2D planar images. This can be while the gantry rotates or with no gantry movement.
[7] In the VolumeView mode, XVI acquires a sequence of 2D projection images while the digital accelerator gantry rotates. XVI uses the acquired images to reconstruct a 3D anatomical volume, which the operator can use for registration with imported CT reference data. This makes sure that the patient position is correct, and shows the target movement.
[8] Symmetry is the acquisition, reconstruction, and registration of a 4D VolumeView. During a Symmetry VolumeView, XVI acquires the images and reconstructs them in relation to the breathing cycle over time. This lets the operator see the different phases of the breathing cycle for a patient.

Intrafraction Imaging	The ImagingRing System, provided that no collision is detected, is capable of acquiring images while the treatment beam is ON.	Intrafraction imaging is an option that lets you acquire kV images during an MV treatment field delivery.
Segmental Technique	The ImagingRing System is capable of interrupting image acquisitions using the proper command.	Lets you use the INTERRUPT button on the FKP to do a pause in a MotionView or VolumeView acquisition.
Distributed Review	The ImagingRing System provides a third party system (e.g. the Radiotherapy Control System of a treatment delivery device) called requestor, with the requested image dataset for image review and further processing.	Distributed Review lets you send data to the patient management information system in which you can do the CBCT image review.
IEC 60601-1	✓	✓
IEC 60601-2-1	-	✓
IEC 60601-1-3	✓	✓
IEC 60601-2-44	✓	✓
IEC 60601-2-54	✓	✓
IEC 62304	✓	✓
IEC 62366	✓	✓
ISO 14971	✓	✓

Table 1: Comparison of technological characteristics of IRS and the predicate XVI R5.0

Characteristics	**ImagingRing System**	**KVue**
510(k)	-	K060671
Manufacturer	medPhoton GmbH	WFR/AQUAPLAST CORP/Qfix
Product code	IYE	JAI
Indications for use		
Used with a charged particle or photon radiation therapy system	✓ limited for use in particle therapy only	✓
Patient setup position	✓	✓
Material		
Advanced fiber composites that contain no metal parts in the treatment area.	✓	✓
Biocompatibility	✓	✓
Interface functionalities		
Mountable on treatment tables using plates with mechanical fixation.	✓	✓
Mechanical properties		
Meets the deflection requirements of IEC 60976 (<5 mm in the specified setup).	< 1 mm effect in imaging volume accuracy N/A	✓
Virtual Indexing	✓	✓

Radiolucent: Aluminum Equivalence Thickness (AET): ~0.6 mm @ 100kVp; Water Equivalence Thickness (WET): 2-6 mm @ 6 MV).	AET = 1.9 mm WET≤16.5 mm	✓

Table 2: Comparison of technological characteristics of IRS and the predicate KVue

The ImagingRing System and the two predicate devices target the same population, i.e., patients undergoing radiotherapy workflows in a hospital environment. Therefore, they are subject to the same human factors and must provide the same compatibility with the environment and interaction with other devices such as - but not limited to - positioning/immobilization devices, radiotherapy treatment delivery systems and patient positioning systems.

The ImagingRing System, like the two predicate devices, can be used for treatment that includes but is not limited to malignant and benign brain tumors, brain metastases, spine lesions, squamous cell carcinoma of the head and neck, lung, breast, pancreatic, hepatic malignancies, prostate, and bone metastases.

The devices create the same functional outputs that support procedures during radiotherapy. This is reflected in the similarity of the indications for use of the devices. The differences in the environmental conditions for operation, gantry movement, electrical data, beam limiting devices, technical specifications, view mode options and attenuation properties do not have impact on safety and effectiveness. Therefore the IRS is considered substantial equivalent for the main functional characteristics and the indications for use.

The ImagingRing System is considered substantial equivalent to the Elekta XVI R5.0 (K131965) and the Qfix kVue (K060671). There is no significant difference in intended use or technology.

Summary of performance testing:
The system is subject to compliance testing to voluntary consensus safety standards.
Details of the standards employed in the design are specified in chapter 9 (Declaration of Conformity and Summary Reports) which includes but not limited to IEC 60601-1, IEC 60601-1-3, IEC 60601-2-54, IEC 62304, IEC 62366 and ISO 14971.
Testing was performed to evaluate the respective safety and performance requirements in the form of module and integration verification as well as system level validation. The results from verification and validation testing prove the conformance to applicable standards and demonstrate that safety & effectiveness have been achieved.

Animal Testing:
medPhoton GmbH did not perform any animal testing for the ImagingRing System.

Clinical Testing:
medPhoton GmbH did not perform any clinical testing for the ImagingRing System.

Conclusion: medPhoton GmbH believes that the ImagingRing System is substantially equivalent to the currently legally marketed devices. The ImagingRing System does not introduce new indications for use, has the same technological characteristics and does not introduce new potential hazards or safety risks.