DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

October 20, 2016

iRT Systems GmbH
% Mr. Dave Yungvirt
CEO
Third Party Review Group, LLC
The Old Station House
24 Lackawanna Place
MILLBURN NJ 07041

Re: K162629
Trade/Device Name: IQM Integral Quality Monitor
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: September 19, 2016
Received: September 21, 2016

Dear Mr. Yungvirt:

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)*

K162629

Device Name
IQM Integral Quality Monitor

Indications for Use *(Describe)*

The IQM Integral Quality Monitor is a large-area ionization chamber intended to be used for quality assurance verification measurements and documentation of the treatment delivery accuracy (beam shape, position and dose) from medical linear accelerators used for intensity modulated radiation therapy.

The data acquired by IQM is used to compare and verify a treatment dose (delivered dose) to the expected dose and to compile treatment delivery radiation beam data over time as part of a quality assurance program.

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.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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# §5 510(k) Summary
# IQM Integral Quality Monitor

The following information is provided following the format of 21 CFR 807.92

## 1 SUBMITTER/HOLDER

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Contact Person: Juergen Oellig

Date Prepared: June 24, 2016

## 2 DEVICE

Name of Device: IQM Integral Quality Monitor (also “IQM” or the “IQM System)

Common or Usual Name: Linear Accelerator. The subject device is a Verification System for Radiation Therapy, an accessory or ancillary device for a Linear Accelerator.

Classification Name: “Medical charged-particle radiation therapy system” and accessory devices (21 CFR 892.5050) (IQM is an accessory device)

Regulatory Class: II

Product Code: IYE

## 3 PREDICATE DEVICE

PTW DAVID, 510(k)# K062817

This predicate device has not been subject to a design-related recall[1].

No reference devices were used in this submission.

[1] Most recent database search from Dec. 21, 2015

# 4 DEVICE DESCRIPTION

The IQM System is designed for the verification of radiation therapy treatments delivered with a linear accelerator. The IQM consists of an electronic detector device and software used to control the device and to process and display the results. Comparisons may be made with expected / previously measured data, results reviewed and documented for quality assurance purposes, and deviations from the expected signal can be detected and reported. Where results can be presented on a segment by segment basis, the realtime reporting of results gives the user the opportunity to detect serious deviations still during treatment, potentially aiding radiation therapy professionals in increasing patient safety.

# 5 INTENDED USE & INDICATIONS FOR USE

**Intended Use Statement**

The IQM Integral Quality Monitor is a large-area ionization chamber intended to be used for quality assurance verification measurements and documentation of the treatment delivery accuracy (beam shape, position and dose) from medical linear accelerators used for intensity modulated radiation therapy.

The data acquired by IQM is used to compare and verify a treatment dose (delivered dose) to the expected dose and to compile treatment delivery radiation beam data over time as part of a quality assurance program.

**Comparison of Statements between Predicate and Subject Devices**

The *Intended Use* statement for the subject device, IQM, is not identical to the predicate device DAVID *Intended Use* statement (see below); however, the statements are very comparable despite small differences in phrasing or word choice. The differences do not describe a substantial difference in use or in the safety and effectiveness of the device relative to the predicate. Both the subject and predicate devices are intended for use in verification of the radiation beam delivered by a linear accelerator. Both systems acquire data during the treatment, and compare these to data acquired before the treatment, and compare these to verify the treatment dose delivered to the dose expected. Both devices allow the compilation of treatment delivery data for quality assurance purposes, such as monitoring for the consistency and accuracy of the treatment delivered.

A detailed comparison of the use statements for the subject and predicate devices is made in chapter 12 of this submission, *Discussion of Substantial Equivalence,* in section 3 *Intended Use*.

# 6 COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

| **Predicate Device** | **Subject Device IQM** | **Conclusion, validation reference** |
|---|---|---|
| Use Environment & User | | |
| At the linear accelerator in the the treatment room with protective bunker in a radiation therapy department. User handling the device is a radiation oncology specialized professional | Same | No difference for safety and effectiveness |
| Supported linear accelerator treatment modality | | |
| Intended for verification of photon beam therapy | Same | No difference for safety and effectiveness |
| Not intended for verification of electron beam therapy. Detector is removed if electron beams are to be used | Same | No difference for safety and effectiveness |
| Detector construction | | |
| Construction & materials: flat, vented ion chamber, for photon energy beams, multiple filaments (wires) electrodes between PMMA | Flat, vented ion chamber, for photon energy beams, angled metal electrode plates in PMMA frame | No safety issue, effectiveness demonstrated with performance data: subject device delivers appropriate linearity, sensitivity & reproducibility |

| | | |
|---|---|---|
| Radiological characteristics: Beam attenuation caused by detector must be considered in TPS | Same | No difference for safety and effectiveness. Handling of beam attenuation is demonstrated in performance data |
| Electrical and mechanical safety characteristics:<br><br>compliance with IEC 60601-1 and IEC 60601-1-2 (EMC) | Same | No difference for safety and effectiveness. Subject device has been tested to newest editions of the Medical Electrical Equipment safety (IEC 60601-1) and MEE EMC (IEC 60601-1-2) standards |
| Detector Dimensions & weight:<br><br>Varies dependent on model, including linac specific holder:<br><br>451mm-498 mm x<br>243mm-372mm x<br>49 mm-99mm<br>approx. 3.5kg-4.9kg | Similar:<br><br>One detector model, overall dimensions & weight vary with linac vendor specific holder:<br><br>450mm-476mm x<br>449mm-462 mm x<br>35mm<br>approx. 6.8kg | No difference for safety and effectiveness |
| Availability of the light field:<br><br>Light field is available (at least 70% translucent) | Light field is made available by removing detector (detector is opaque) | No difference for safety and effectiveness.<br><br>Detector holder to attach subject device to a linear accelerator is constructed for easy removal and attachment and is automatically recognized by accessory code recognition system of linac, as validated in system and usability testing. |
| Fixation of detector to treatment machine: | Similar | No difference for safety and effectiveness. |

| | | |
|---|---|---|
| Mechanical fixation & optical-mechanical coding plugs on the device holder, per the specification / implementation of the respective linac manufacturer | | Detector holder to attach subject device to a linear accelerator is constructed for easy removal and attachment and is automatically recognized by accessory code recognition system of linac, as validated in system and usability testing. |
| Energy Source | | |
| Detector powered with rechargeable NiMH battery pack | Detector powered with rechargeable Lithium ion battery pack | No difference for safety and effectiveness; Battery and battery implementation in subject device have been tested to newest MEE (IEC 60601-1) and rechargeable battery (IEC 62133) standards |
| Transceiver power via power supply connected to mains | Same | No difference for safety and effectiveness. |
| Energy delivered | | |
| No energy is delivered to patient or to another system | Same | No difference for safety and effectiveness |
| Communication: | | |
| Wireless transmission of signal between detector and transceiver via Bluetooth | Same | No difference for safety and effectiveness |
| Physical cable connection between transceiver and computer in control room through RS323 cable | Same | No difference for safety and effectiveness |

| Measurement Principle | | |
|---|---|---|
| Relative dosimetry using measured dose length product, correlating to the opening of an MLC leaf pair and the supplied dose | Relative dosimetry using measured spatially-sensitive large area dose product, correlating to the opening of all MLC pairs (entire beam shape) and the supplied dose | No difference for safety and effectiveness. Subject device IQM has been validated as acquiring the entire beam shape and dose as required for verification, demonstrated in the performance data |
| Specification of reproducibility of </= 1% or better; non-linearity </=1% or better | Same | No difference for safety and effectiveness. IQM performance (sensitivity, reproducibility, linearity) is demonstrated in the performance data. |
| Software functionalities provided | | |
| Extent of software provided:<br>Software provided to control data acquisition (measurement), derive/ save the expected / reference values against which each session is compared, to compare data, to display and save results, retrieve data for reports | Same | No difference for safety and effectiveness. Software design, development and verification are performed per IEC 62304 and validated in conformance with ISO 13485, GMP and the FDA Guidance for Software Validation |

# 7 PERFORMANCE DATA

The FDA has not established any performance standards for this product.

**Bio-compatibility**

Bio-compatibility is not a concern because there is no contact with the patient, including no indirect contact. The IQM hardware can be handled without reservation by all users.

**Electrical & mechanical safety and electromagnetic compatibility (EMC)**

Electrical safety and EMC testing were conducted on the IQM by an independent accredited (IEC 17025) laboratory and is certified as in compliance with the IEC 60601-1 (ed. 3.1, AAMI/ANSI ES 60601-1:2005+A2012) standard for safety and the IEC 60601-1-2 (2014, ed. 4) standard for EMC. IQM uses a rechargeable lithium ion battery which was tested for safety to IEC 63122 by an independent accredited (IEC 17025) laboratory.

**Software Verification and Validation Testing**

Software verification and validation testing were conducted and documentation provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices."

The IQM is an accessory to a medical linear accelerator, itself a device considered as a "major" level of concern. Detailed documentation concerning software verification and validation have therefore been provided in accordance with the guidance. As a device intended to verify and document the accuracy of the treatment delivery, but not to deliver, plan, simulate or control delivery, the IQM itself can be categorized as of "minor" level of concern, since a failure or latent flaw in the software cannot result in injury or death to the patient or operator.

**Bench & Non-clinical Testing**

Verification and validation testing demonstrated that the device performance and functionality fulfill the design specifications and that the device performs the intended use and meets users' needs.

The performance of IQM as a measurement device were evaluated in bench tests conducted by iRT as manufacturer in multiple hospital environments where the IQM was installed and tested in the clinical workflow, with each hospital's clinical equipment and network environment. Performance testing evaluated how the device detected deviations and lack of deviations in beam intensity, shape and position as well as the reproducibility of measurement results. Test users at 17 sites participated in various tests and were observed in their handling and interaction with the device as part of human factors / usability testing.

Testing with a patient present (clinical testing) was not required because all tasks in the IQM's clinical workflow and its measurement results are the same whether or not a patient is present. Testing was performed with production equivalent IQM units, under clinically representative conditions with Elekta and

Varian brand linear accelerators, commissioned and used clinically at the respective hospitals. Testing was performed by qualified personnel, through iRT staff and hospital medical physicists and radiation therapists at the respective hospital locations.

# 8 CONCLUSIONS

The comparison of the indication for use, performance, safety and effectiveness of the predicate and subject devices demonstrates that the IQM is as safe and effective as the predicate device and performs as well or better for its application. The technological differences between the predicate device and IQM do not raise new or different questions of safety and effectiveness.