PTW-Freiburg Physikalisch-Technische-Werkstaetten Dr. Pychlau GmbH
Dr. Sandor-Csaba Ats
Regulatory Affairs Manager
Loerracher Str.7
Freiburg, 79115 BW
GERMANY

October 20, 2017

Re: K160405
Trade/Device Name: OCTAVIUS
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: September 29, 2017
Received: October 2, 2017

Dear Dr. Ats:

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 (DICE) 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 (DICE) 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,

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)*
K160405

Device Name
OCTAVIUS

Indications for Use *(Describe)*

The OCTAVIUS System is intended to collect beam data for patient plan verification of a treatment planning system (TPS) and under the aspect of machine QA for the following purposes:
- IMRT patient plan verification
- periodic QA procedures, e.g. constancy checks
- beam data analysis according to international therapy dosimetry protocols
- measurements after repair or replacement of major treatment unit components

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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510(k) Summary

1.	Applicant:	PTW-Freiburg Physikalisch-Technische-Werkstaetten Dr. Pychlau GmbH
2.	Address:	Loerracher Strasse 7 79115 Freiburg Germany www.ptw.de
3.	Contact Person:	Dr. Sándor-Csaba Áts Tel. +49 (0) 761 49055 896 sandor.ats@ptw.de
4.	Preparation Date:	September 5, 2017
5.	Device Name:	OCTAVIUS
6.	Proprietary Name:	OCTAVIUS
7.	Common Name:	Dosimetric Quality Assurance for Patient Specific Radiation Treatment
8.	Classification:	Regulation number: 21 CFR 892.5050 Name: Medical charged-particle radiation therapy system, Product Code: IYE
9.	Predicate Device:	Sun Nuclear's "MapCHECK2" and "ArcCHECK" (K131466)
10.	Device Description:	The OCTAVIUS System is comprised of a two-dimensional ion chamber based detector array, uniformly arranged as a matrix and a separate detector interface for data acquisition. The detector array can be placed either in a static cubic or octagonal phantom or in a linear rotational phantom. For the measurement of moving radiation sources (e.g. the rotating gantry of a LINAC), the rotational phantom rotates synchronously with the gantry. An inclinometer, fixed to the gantry, delivers the gantry angle values which are used to align the rotating detector to the gantry. The whole system is controlled with software for data display and processing.
11.	Intended Use:	The PTW OCTAVIUS System is used for dosimetry measurements in the context of a radiotherapy system, e.g. a medical linear accelerator (LINAC), electron or photon beams, a particle therapy system or a Cobalt-60 treatment machine. The device is intended for the measurement of dose distributions and the comparison with the data as calculated by the treatment planning system (patient plan verification) and/or for periodic quality assurance procedures according to the QA plan of the responsible medical physicist (e.g. constancy checks).

12.	Indications:	The OCTAVIUS System is intended to collect beam data for patient plan verification of a treatment planning system (TPS) and under the aspect of machine QA for the following purposes: – IMRT patient plan verification – periodic QA procedures, e.g. constancy checks – beam data analysis according to international therapy dosimetry protocols – measurements after repair or replacement of major treatment unit components
13.	Contraindications:	The OCTAVIUS System is for QA purposes and must not be used while a patient is present. It must not be used for Diagnostic Radiology. The resulting measurement data is for data verification of the patient plan and must not be used to control the radiotherapy device by importing the data into the therapy patient plan.
14.	Intended User:	The OCTAVIUS System must be used only by qualified personnel, usually the medical physicists responsible for the radiotherapy system or an authorized person.
15.	Substantial equivalence	The characteristics of this device are similar to those of the predicate devices identified on the comparison chart, which is provided with the premarket notification submission. It is our opinion that the OCTAVIUS does not have technological characteristics that raise additional types of questions related to terms of safety and effectiveness.
	Differences to the predicate devices:	OCTAVIUS provide ion chambers for radiation detection while predicate devices utilize semiconductor technology. Both methods are used since many years and provide equal performance and accuracy. No additional safety issue is raised by using different detector types.
16.	Performance Data:	The FDA has not published any performance standards for this product.
	Biocompatibility:	The device is used for pre-treatment quality assurance while no patient is present. Since the contact of the operator with the device occurs only with uninjured skin and the surface of the device components contains no critical material, the contact with the operator is biologically uncritical.
	Electrical & mechanical safety and electromagnetic compatibility (EMC):	Electrical safety and EMC testing were conducted by independent test laboratories. OCTAVIUS is certified as in compliance with IEC 61010-1:2010 (with no patient contact of the product the focus is directed to user safety) and IEC 61326-1:2012 (emission and immunity) / CISPR 11:2009+A1:2010 (RF technology) and 47 CFR Part 15 Subpart B.

Software Verification and Validation Testing:	Software verification and validation testing results were conducted and submitted according to the Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (2005).
Bench and Non-clinical Testing:	Verification and validation testing demonstrated that OCTAVIUS fulfils the design specification and its intended use. Non-clinical performance testing was performed closely based on the IEC 60731 A1:2016 which was originally addressed to single detector dosimetry systems. Further tests were performed to verify specific properties of detector array phantom systems which included radiotherapy dose measurements i.e. accuracy of dose measurements and of the correct positioning of the detector aligned to the gantry movement. The verification of the design output against the design input was performed in OCTAVIUS system testing. Validation of the clinical workflow has been conducted in OCTAVIUS validation testing with qualified medical physicists and experienced PTW staff. Testing with a patient present was not required since OCTAVIUS acts as a pre-treatment quality assurance while no patient is present.
17. Conclusions:	The comparison of the indications for use, the technological characteristics, the performance, safety and effectiveness of the predicate and the subject device has shown that the PTW OCTAVIUS System is as safe and effective as the predicate device and that the application is as well or better. With respect to the use the device do not raised new questions of safety and effectiveness.