IBA Dosimetry GmbH
% Olaf Teichert
Official Correspondent
TUV SUD America, Inc.
1775 Old Highway 8 NW
NEW BRIGHTON, MN 55112

January 23, 2020

Re: K191821
Trade/Device Name: Blue Phantom PT
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: Class II
Product Code: LHN
Dated: June 27, 2019
Received: July 8, 2019

Dear Olaf Teichert:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For

Thalia Mills, Ph.D.
Chief
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191821

Device Name
Blue Phantom PT

Indications for Use *(Describe)*

The intended use of Blue Phantom PT is to move detectors in one dimension within a water tank. It transfers indicated ionization beams (proton beams) at a certain position into electrical signals.

Non-intended use of Blue Phantom PT
The Blue Phantom PT is not meant for measurement orthogonal to the proton beam (inline and crossline measurements).

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
BLUE PHANTOM PT

PROTECT +
ENHANCE +
SAVE LIVES

IBA DOSIMETRY GMBH
Bahnhofstrasse 5, 90592 Schwarzenbruck, Germany

510(k) Summary

Date of preparation	1/22/2020
Submitter	IBA Dosimetry GmbH Bahnhofstr. 5 90592 Schwarzenbruck Germany
Contact Person	Andreas Suchi Executive Director QRS Andreas.Suchi@iba-group.com Phone: +49 9128 607-943 Fascimile: +49 9128 607-10
Common Name	BP PT
Classification Name	Medical charged-particle radiation therapy system
Trade Name	Blue Phantom PT
Class	II
Panel	Radiology
Classification regulation	21CFR 892.5050
Product Code	LHN
Predicate Device	WP 1D (K032594)

1. Intended Use

1.1. Intended use of Blue Phantom PT

The intended use of Blue Phantom PT is to move detectors in one dimension within a water tank. It transfers indicated ionization beams (proton beams) at a certain position into electrical signals.
Non-intended use of Blue Phantom PT:
The Blue Phantom PT is not meant for measurement orthogonal to the proton beam (inline and crossline measurements).

1.2. Intended use of WP 1D

The Clinical Reference Dosimetry Phantom WP1D is used to position various radiation detectors in water or air. It consists of a cubic tank and precision one-dimensional hand crank or motor driven servo. By design it is suitable to act as a phantom according to various dosimetric protocols (e.g. AAPM´s TG-51 or IAEA´s TRS-398). The device is intended to be used by experienced professionals entrusted with dosimetric functions only.

2. Product Description

2.1. Blue Phantom PT

The Blue Phantom PT system consists of a water tank with a one-dimensional servo including a common control unit (CCU PT) with integrated two-channel electrometer. An ionisation chamber (e.g. Stingray) is placed inside the Blue Phantom PT with a holder and is used as detector for measurements.
The Blue Phantom PT is intended to be used in the magnetic environment of a proton therapy treatment unit and its technology has been designed to meet those requirements.
Figure 1 shows the Blue Phantom PT and the CCU.

Figure 1: BluePhantom PT with CCU

Blue Phantom PT water phantom *CCU PT*

On the horizontal Y-rail, detector holders for various detectors can be mounted on a sliding shoe. The detector can be positioned in the Y-direction for measuring horizontal beams.

2.2. WP 1D

The WP1D phantom consists of a cubic tank and a one-dimensional moving mechanics to move the detector up and down along the Z-axis. The tank has a water inlet/outlet that is equipped with a quick coupler for easy connection of the water-filling tube. Three adjustable feet support the tank and provide horizontal leveling adjustment.

3. Device Characteristics

Table 1: Device Characteristics

Characteristic	WP 1D	Blue Phantom PT
Operating Principle	WP 1D is a one-dimensional water phantom intended for reference dosimetry. A detector is positioned in the phantom and can be adjusted in different depths either electronically or manually with a hand crank. In case of electronic positioning, the OmniPro-Accept 6 (K011763)	BP PT is a one-dimensional water phantom intended for reference dosimetry. A detector is positioned in the phantom and is electronically adjusted in different depths. The myQA Accept (K011763) software is used for depth dose

	software is used for depth dose measurement and controlling the detectors positioning.	measurement and controlling the detectors positioning.
Sensortype	Magneto-restrictive	Inductive
Electrometer	Separate device	Embedded in control unit CCU
Tank size	36x42x36 cm	51.4 x 27.7 x 26.8 cm
Tank wall material	Acrylic (PMMA)	Acrylic (PMMA)
Wall thickness	10mm	10mm
Thin window	N/A	5mm / 3mm
Position resolution	0.1mm	0.1mm
Position accuracy	±0.4 mm	±0.05 mm
Reproducibility	±0.1 mm	±0.03 mm
Maximum scan range	25 cm	38 cm max.
Positioning speed	25mm/s	Max. 25mm/s
Scanning speed (continuous measurement)	Not applicable, this is not part of its application scope	max. 20mm/s

4. Performance testing

BP PT was successfully tested to demonstrate safety and effectiveness and substantial equivalence to the predicate device. It was subject to the following tests:

- System test
- Clinical environment test
- Usability test
- Unit test (Mechanics)
- Firmware test
- Non-clinical test against the following standards:

Standard	**Test Method**	**Compliance**
ISO 14971:2007	Internal testing	yes
IEC 61010-1: 2010	Tested by external test house	yes
IEC 62304:2006 + A1:2015	Internal testing; FDA guidance documents have been applied	yes
IEC 62366-1:2015	Internal testing	yes
IEC 61326-1:2012	Tested by external test house	yes
AAMI RT2:2017	Internal testing	yes

Animal and clinical test were not required to demonstrate safety and effectiveness.
Requirements of the tests were met as specified in the test requirements and the applied standards.

5. Conclusion

The operating principle of the BP PT and its predicate is identical and the performed tests proof that the differences between BP PT and WP 1D do not raise new questions of safety and effectiveness. The indication for use statements are slightly different, since BP PT is used for proton beams, while WP 1D is used for ionizing radiation like photon and electron radiation, but excluding proton radiation. This difference in radiation type is compensated with an equally safe and effective new inductive sensor.
Despite, the intended use of BP PT is more limited than of WP 1D. The evaluation and performed tests provide reasonable assurance that the differences are not critical to the intended use of the device, and that they do not affect the safety and effectiveness of the device when used as labeled.