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

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.


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
Indications for Use

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)

[X] 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
BLUE PHANTOM PT

IBA DOSIMETRY GMBH
Bahnhofstrasse 5, 90592 Schwarzenbruck, Germany
**510(k) Summary**

Date of preparation 1/22/2020

Submitter IBA Dosimetry GmbH
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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: Blue Phantom PT with CCU*

![Blue Phantom PT and CCU](image)

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*

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>WP 1D</th>
<th>Blue Phantom PT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operating Principle</td>
<td>WP 1D is a one-dimensional water phantom intended for reference dosimetry. A detector</td>
<td>BP PT is a one-dimensional water phantom intended for reference dosimetry. A detector</td>
</tr>
<tr>
<td></td>
<td>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)</td>
<td>is positioned in the phantom and is electronically adjusted in different depths. The myQA Accept (K011763) software is used for depth dose</td>
</tr>
</tbody>
</table>
Abbreviated 510(k) for Blue Phantom PT, class II Medical Device

<table>
<thead>
<tr>
<th>Sensor type</th>
<th>Magneto-restrictive</th>
<th>Inductive</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electrometer</td>
<td>Separate device</td>
<td>Embedded in control unit CCU</td>
</tr>
<tr>
<td>Tank size</td>
<td>36x42x36 cm</td>
<td>51.4 x 27.7 x 26.8 cm</td>
</tr>
<tr>
<td>Tank wall material</td>
<td>Acrylic (PMMA)</td>
<td>Acrylic (PMMA)</td>
</tr>
<tr>
<td>Wall thickness</td>
<td>10mm</td>
<td>10mm</td>
</tr>
<tr>
<td>Thin window</td>
<td>N/A</td>
<td>5mm / 3mm</td>
</tr>
<tr>
<td>Position resolution</td>
<td>0.1mm</td>
<td>0.1mm</td>
</tr>
<tr>
<td>Position accuracy</td>
<td>±0.4 mm</td>
<td>±0.05 mm</td>
</tr>
<tr>
<td>Reproducibility</td>
<td>±0.1 mm</td>
<td>±0.03 mm</td>
</tr>
<tr>
<td>Maximum scan range</td>
<td>25 cm</td>
<td>38 cm max.</td>
</tr>
<tr>
<td>Positioning speed</td>
<td>25 mm/s</td>
<td>Max. 25 mm/s</td>
</tr>
<tr>
<td>Scanning speed (continuous measurement)</td>
<td>Not applicable, this is not part of its application scope</td>
<td>max. 20 mm/s</td>
</tr>
</tbody>
</table>

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:

<table>
<thead>
<tr>
<th>Standard</th>
<th>Test Method</th>
<th>Compliance</th>
</tr>
</thead>
<tbody>
<tr>
<td>ISO 14971:2007</td>
<td>Internal testing</td>
<td>yes</td>
</tr>
<tr>
<td>IEC 61010-1: 2010</td>
<td>Tested by external test house</td>
<td>yes</td>
</tr>
<tr>
<td>IEC 62304:2006 + A1:2015</td>
<td>Internal testing; FDA guidance documents have been applied</td>
<td>yes</td>
</tr>
<tr>
<td>IEC 62366-1:2015</td>
<td>Internal testing</td>
<td>yes</td>
</tr>
<tr>
<td>IEC 61326-1:2012</td>
<td>Tested by external test house</td>
<td>yes</td>
</tr>
<tr>
<td>AAMI RT2:2017</td>
<td>Internal testing</td>
<td>yes</td>
</tr>
</tbody>
</table>

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 prove 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.