IBA Dosimetry GmbH
℅ Mr. Dave Yungvirt
CEO, Official Correspondent
Third Party Review Group, LLC
25 Independence Blvd.
WARREN NJ 07059

July 17, 2020

Re: K201798
Trade/Device Name: myQA iON
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: Class II
Product Code: LHN, IYE
Dated: June 28, 2020
Received: June 30, 2020

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. 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 T. Mills, Ph.D.
Director
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

4. Indication for Use Statement

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)*

K201798

Device Name
myQA iON

Indications for Use *(Describe)*

The intended use of the myQA iON product is to perform patient quality assurance activities for radiation therapy treatment delivery systems. myQA iON is a software toolbox allowing the Medical Physicist to perform quality assurance activities before and after the patient treatment fractions for all patients undergoing radiation therapy.

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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5. 510(k) Summary of 510(k) Statement

510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date: January 17th, 2019 K201798

1. 510(k) Holder:

Company: IBA Dosimetry GmbH

Attention: Andreas Suchi, Executive Director QRS

Adresse: Bahnhofstrasse 5, 90592 Schwarzenbruck – Germany

Phone: +49 9128 607943

Fax : +49 9128 607-10

Email : Andreas.Suchi@iba-group.com

2. Device

Trade Name	myQA iON
Common Name	Patient Quality Assurance Software
Classification Name	Medical Charged –Particle Therapy Systems
Classification regulation	21 CFR § 892.5050
Classification Code	Main Product Code: LHN, Second Product Code: IYE

3. Predicate Device

The myQA iON product for Patient quality assurance in radiation therapy is substantially equivalent to the cleared product Mobius Medical Systems, Mobius3D (K153014). The intended uses are the same as well as the technological characteristics.

4. Device Description

The myQA iON product is a server-based software application for performing patient quality assurance for radiation therapy. In its full scope, the product delivers means for the verification of:

- The patient treatment plan prior to the first treatment fraction by
  - Using an independent dose algorithm to compute a dose map based on the patient treatment plan;

        - Performing measurements using external measurement devices and analyzing the results;
        - Performing machine log analysis during a treatment dry run session and reconstructing the delivered dose.
    - The patient treatment delivery by
        - Performing machine log analysis and reconstructing the delivered dose for each treatment fraction.

In its full scope, the product interfaces with the Treatment Planning System, the Oncology Information System, the treatment delivery System and the external measurement device.

5. Intended Use

The intended use of the myQA iON product is to perform patient quality assurance activities for radiation therapy treatment delivery systems. myQA iON is a software toolbox allowing the Medical Physicist to perform quality assurance activities before and after the patient treatment fractions for all patients undergoing radiation therapy.

6. Non-Intended Use

The product is not intended to be a treatment planning system, nor is it intended to have direct or indirect contact with patients.

7. Intended User

The product is designed to be used by trained radiation oncology health professionals only.

The typical users of myQA iON are the certified Medical Physicists and technicians/dosimetrists in the radiation therapy department. The users are skilled and trained to practice patient QA activities in a clinical environment.

8. Summary of Technological Characteristics compared to the predicate device

The myQA iON and the Mobius3D (K153014 - predicate device) products are identical in terms of intended use, principles of operation and clinical performance. The difference between both systems is the type of radiation therapy they are used for.

The following table gives a high-level overview of the technical characteristics

Characteristics	myQA iON	Mobius3D	Comment
DICOM handling -manual import -automatic import -export	 Yes Yes No	 Yes Yes Yes	The export is not needed to fulfill the intended use of myQA iON
Independent dose calculation	Yes	Yes	
Analysis of external measurements of radiation fields	Yes	Yes	myQA iON provides a wider panel of analysis tools based on the physical measurements of radiation fields through the analysis of manually uploaded machine log files and manually uploaded MatriXX measurement files (MatriXX, FDA listing Number D032576, IBA Dosimetry GmbH).
Gamma analysis	Yes	Yes	
Patient QA report generation	Yes	Yes	
Server based	Yes	Yes	myQA iON can be accessed via web-browser from any computer connected to the (private) network
Email notification	No	Yes	not required to fulfill myQA iON intended use
Evaluation settings modification	Yes	Yes	
Plan approval	Yes	Yes	
PDF export of patient QA report	Yes	Yes	

The differences between the products in the table above do not influence the safety and effectiveness of the myQA iON device nor does it prevent it from fulfilling its intended use.

The difference between myQA iON and the Mobius3D devices lies in the area of application. While both are designed to perform patient quality assurances tasks for radiation therapy, the Mobius3D focuses on radio-therapy whereas the myQA iON focuses on proton therapy.

We believe that in the present case, this difference is neglectable to prove substantial equivalence. Indeed, the clinical workflows are identical for both proton and radio-therapy patient quality assurance. In both cases, the treatment plan is created in DICOM format on the treatment planning system and exported to the quality assurance platform. The platform then computes an independent dose using a Monte Carlo dose engine and allows the user to complement the analysis by using machine irradiation log and ion chamber measurements at the isocenter.

9. Environment of Use

The typical environment of use for myQA iON is the radiation therapy center. However, as myQA iON is a web application, the environment of use can vary depending on the location of the user.

10. Summary of Non-Clinical Test

IBA Dosimetry performed system and software level tests to assess the performance of the myQA iON product. The following tests have been provided in support of the substantial equivalence determination:

- Risk Analysis Testing verifying the implementation of the identified hazard mitigation;
- Software Testing verifying the correct software implementation;
- Physics Testing verifying the correct behavior of the physics algorithms;
- Integration Testing verifying the correct integration of the different software components;
- System Testing verifying the correct implementation of the clinical workflow;
- Beta Testing validating the usability of the software.

11. Summary of Clinical Test

The subject of this premarket submission, the IBA Dosimetry myQA iON product, did not require clinical testing to support substantial equivalence to the predicate device.

12. Conclusion

The verification and validation activities ensure that the IBA Dosimetry myQA iON product provides substantial equivalence in terms of safety, effectiveness and performance to the predicate device.