



September 23, 2026

ProNova Solutions
Amy Bellendir
QARA Manager
330 Pellissippi Place
Maryville, Tennessee 37804

Re: K260597
Trade/Device Name: VIRTUE QA
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical Charged-Particle Radiation Therapy System
Regulatory Class: Class II
Product Code: LHN
Dated: August 17, 2026
Received: August 18, 2026

Dear Amy Bellendir:

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 (the 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 available 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.

FDA's substantial equivalence determination also included the review and clearance of your Predetermined Change Control Plan (PCCP). Under section 515C(b)(1) of the Act, a new premarket notification is not required for a change to a device cleared under section 510(k) of the Act, if such change is consistent with an

established PCCP granted pursuant to section 515C(b)(2) of the Act. Under 21 CFR 807.81(a)(3), a new premarket notification is required if there is a major change or modification in the intended use of a device, or if there is a change or modification in a device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process. Accordingly, if deviations from the established PCCP result in a major change or modification in the intended use of the device, or result in a change or modification in the device that could significantly affect the safety or effectiveness of the device, then a new premarket notification would be required consistent with section 515C(b)(1) of the Act and 21 CFR 807.81(a)(3). Failure to submit such a premarket submission would constitute adulteration and misbranding under sections 501(f)(1)(B) and 502(o) of the Act, respectively.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

A handwritten signature in black ink, reading "Lora D. Weidner". The signature is fluid and cursive, with the first name "Lora" and last name "Weidner" clearly distinguishable. A large, light blue "FDA" watermark is visible in the background behind the signature.

Lora D. Weidner, Ph.D.
Assistant Director
Radiation Therapy Team
DHT8C: Division of Radiological
Imaging and Radiation Therapy Devices
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.

K260597

?

Please provide the device trade name(s).

?

VIRTUE QA

Please provide your Indications for Use below.

?

VIRTUE QA is an integrated software platform for patient-specific quality assurance, treatment plan verification, and patient setup review in proton radiation therapy. VIRTUE QA supports QA activities performed both before and during the course of treatment for all patient populations receiving proton radiation therapy. VIRTUE QA is not a treatment planning system. It does not generate, modify, or transmit instructions to any treatment delivery device, nor does it control any aspect of treatment delivery to patients.

Please select the types of uses (select one or both, as applicable).

☒ Prescription Use ([21 CFR 801 Subpart D](#))

☐ Over-The-Counter Use ([21 CFR 801 Subpart C](#))

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510(k) Summary

Submission Number: K260597
Date Prepared: September 18, 2026
Submitter: ProNova Solutions, LLC
Address: 330 Pellissippi Pl, Maryville, TN 37804
Contact: Amy Bellendir
Telephone: (865) 862-4100

1. Device Identification

Device Trade Name: VIRTUE QA
Device Common Name: Patient-Specific Quality Assurance Software
Regulatory Classification: Class II
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical Charged-Particle Radiation Therapy System
Product Code: LHN
R only

Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.

2. Predicate and Reference Devices

	Subject Device	Predicate Device	Reference Device
Device Name	VIRTUE QA	myQA iON	Mobius3D
Manufacturer	ProNova Solutions, LLC	IBA Dosimetry GmbH	Mobius Medical Systems, LP
510(k) Number	K260597	K201798	K153014
Classification	Class II	Class II	Class II

	Subject Device	Predicate Device	Reference Device
Product Code	LHN	LHN, IYE	IYE

Rationale for Predicate Selection:

myQA iON (K201798) is the most appropriate predicate because it shares the same core intended use (patient-specific quality assurance for radiation therapy), utilizes the same fundamental QA methodology (log-file analysis with gamma comparison and independent dose calculation), and operates in a substantially equivalent clinical setting.

Rationale for Reference Device:

Mobius3D (K153014) is cited solely to support VIRTUE QA's offline image review capability (CBCT-to-planning-CT registration for patient alignment verification), which is not present in the predicate device myQA iON but is present in Mobius3D.

3. Indications for Use

VIRTUE QA is an integrated software platform for patient-specific quality assurance, treatment plan verification, and patient setup review in proton radiation therapy. VIRTUE QA supports QA activities performed both before and during the course of treatment for all patient populations receiving proton radiation therapy. VIRTUE QA is not a treatment planning system. It does not generate, modify, or transmit instructions to any treatment delivery device, nor does it control any aspect of treatment delivery to patients.

4. Device Description Summary

VIRTUE QA is a software-only medical device platform comprising four complementary analysis modules and a unified clinical interface:

- **LogIQ Patient QA** — Analyzes treatment machine log files to verify delivery accuracy against planned parameters using gamma analysis and tolerance-based checks.
- **SyntheticIQ Patient QA** — Uses AI/ML models to predict delivered machine parameters without requiring physical beam delivery, enabling pre-treatment QA verification using the same clinical outputs and acceptance criteria as log-file analysis.
- **DupliQate** — Performs independent secondary dose calculation using MCsquare (Monte Carlo simulation) to verify treatment planning system dose calculations.
- **SmaRT Chart** — Automates patient chart reviews to ensure treatment delivery compliance across the course of treatment.
- **Offline Image Review** — Registers daily CBCT images with the planning CT for patient positioning verification.

5. Technology Comparison

Characteristic	VIRTUE QA (Subject)	myQA iON (Predicate)	Comparison
DICOM Import (Manual + Automatic)	Yes	Yes	Equivalent
Analysis of System Log-Files	Yes	Yes	Substantially Equivalent
Gamma Analysis	Yes	Yes	Equivalent
Server-Based Architecture	Yes	Yes	Equivalent
Independent Dose Calculation	Yes	Yes	Equivalent

Characteristic	VIRTUE QA (Subject)	myQA iON (Predicate)	Comparison
Pre-treatment: Log-file QA (dry run)	Yes	Yes	Equivalent
Pre-treatment: Predictive QA (no beam)	Yes	No	New capability
Post-treatment: Log-file QA (per fraction)	Yes (automatic)	Yes	Substantially Equivalent
Patient QA Report Generation / PDF Export	Yes	Yes	Equivalent
Plan Approval Workflow	Yes	Yes	Equivalent
Interfaces with TPS, OIS, TCS	Yes	Yes	Equivalent
Offline Image Review	Yes	No	Supported by reference device (Mobius3D)

Primary Technological Difference: VIRTUE QA implements AI-based predictive QA (SynthetIQ Patient QA) that predicts treatment delivery parameters without requiring physical beam delivery. The predicate device performs pre-treatment QA by analyzing a dry-run beam delivery. VIRTUE QA also includes the same log-file QA capability as the predicate device.

The technological differences do not raise different questions of safety and effectiveness. Both devices must demonstrate accuracy, reliability, error detection capability, and clinical utility — the same fundamental questions regardless of whether QA data comes from AI prediction or physical measurement.

6. Substantial Equivalence Determination

Performance evaluation findings support the conclusion that VIRTUE QA is as safe and as effective as the predicate device. VIRTUE QA and the predicate device share the same intended use, serve the same patient populations, are used in the same clinical environment by the same intended users, and address the same clinical need for patient-specific quality assurance.

The risk assessment demonstrates that the risk profile of VIRTUE QA is comparable to the predicate device. Risks specific to AI-based prediction are mitigated through a three-layer validation framework consisting of per-spot output bounds, aggregate model acceptance criteria, and continuous clinical performance monitoring.

7. AI/ML Training and Validation

7.1 AI-Enabled Function and Training Data

SynthetIQ Patient QA is a machine-specific predictive quality-assurance function. It uses prescribed treatment-machine delivery parameters to predict expected delivery characteristics for pre-treatment QA review.

Models are trained using paired treatment-plan and treatment-delivery records collected from the same treatment machine. Treatment records pass through the shared LogIQ/SynthetIQ ingestion and classification pathway before any training-database update; SynthetIQ does not independently create training data. Ground truth is obtained from machine-recorded delivery data, and no manual labeling or clinical outcome annotation is used. MACHINE_QA, RE-SEARCH, and SERVICE deliveries are excluded from training. Clinical-intent or missing-intent deliveries recorded as fraction zero are classified as log-file QA deliveries and are also excluded.

Each treatment machine maintains an independent training dataset; data and model parameters are not pooled or shared across treatment machines or clinical sites. The retained dataset is refreshed as new eligible clinical deliveries become available. The number of contributing patients varies with the clinical volume and treatment patterns of the individual machine.

7.2 Patient Characteristics and Evaluation Coverage

SyntheIQ predicts treatment-machine behavior rather than patient anatomy or clinical outcome. It does not use patient images, age, sex, race, ethnicity, diagnosis, anatomy, or other demographic characteristics as prediction inputs.

The performance evaluation included:

- 324 patients and 15,565 beam deliveries in the longitudinal predictive-versus-log-file dose-profile evaluation;
- 100 randomly selected patients in the predictive-versus-clinical-log-file detectability comparison;
- 22 clinical plans comprising 55 beams in the independent physical-measurement validation;

Testing covered fixed-beam and gantry treatment rooms, multiple disease sites and plan complexities, the clinically used energy/range and field-position envelope, and nearly the full gantry-angle range.

7.3 Independence of Test Data

Test plans are registered by RTPLAN UID and automatically excluded from the training dataset. A machine-specific comprehensive test plan used during commissioning and daily validation is likewise sequestered from training.

Clinical walk-forward validation provides additional independent evidence. Predictions are generated before treatment and compared with delivery records that did not exist when the predictions were made. The active model remains unchanged throughout the clinical day; eligible delivery data accumulated during that day are used only during a subsequent scheduled retraining cycle.

7.4 Performance Metrics and Acceptance Criteria

The principal performance requirements applied to the evaluated system are:

Metric	Acceptance Criterion
Dose-distribution agreement	$\geq 90\%$ gamma pass rate at 2%/2 mm or $\geq 95\%$ at 3%/3 mm; dose threshold $\leq 10\%$
Spot position	Mean prediction error ± 2 SD within 1 mm
Spot size	Mean percent error ± 2 SD within 15%
Monitor units	Beam-level mean prediction error ± 2 SD within 1%
Physical-output validation	Each predicted spot remains within the commissioned treatment-machine operating envelope

Daily candidate model sets are also evaluated against predefined tolerances for held-out performance, localized training residuals, and sequestered test-plan performance relative to approved baselines. An error-level candidate model set is not activated; the prior validated model set remains in clinical use.

7.5 Bench and Clinical Performance Results

The VIRTUE QA performance evaluation included six complementary studies:

Predictive-versus-log-file dose-profile comparison. A longitudinal evaluation included 324 patients and 15,565 beam deliveries. Mean direct predicted-versus-log-reconstructed dose-profile gamma agreement ranged from 99.59% to 99.92% by treatment room. Fourteen deliveries (0.09%) were below the 90% direct-agreement threshold and underwent root-cause review. The overall correlation between predicted-versus-prescribed and log-reconstructed-versus-prescribed gamma was 0.9749.

A separate parameter-level analysis included 29,094,093 spots from 4,859 beams. Position 95% limits of agreement were within ± 0.24 mm, spot-size limits of agreement were approximately within $\pm 7\%$, and beam-level monitor-unit limits of agreement were -0.58% to $+0.92\%$. The evaluation covered the clinically used energy/range, field-position, gantry-angle, and spot-output envelope.

Predictive QA versus clinical log-file QA detectability. A retrospective study of 100 randomly selected patients used independently established delivery outcomes to compare the two methods at the same 90% gamma threshold. Predictive QA detected 52 of 68 deliverability issues (76.5% sensitivity) and had 98.8% specificity. Clinical log-file QA detected 15 of 68 issues (22.1% sensitivity) in that analysis. The study included TP, TN, FP, and FN classification, confidence intervals, statistical testing, and root-cause analysis.

Independent physical-measurement validation. Twenty-two clinical plans comprising 55 beams were compared with independent array detector measurements across fixed-beam and gantry treatment rooms. Fifty-four beams initially met the 3%/3 mm, $\geq 95\%$ gamma criterion. One highly modulated beam was remeasured with higher-resolution radiochromic film; both SynthetIQ and LogIQ achieved 98.3% gamma agreement on film. All 55 beams met the study acceptance criterion.

Perturbation-sensitivity testing. Controlled position, spot-size, and monitor-unit perturbations challenged the production daily-retraining and monitoring process over 24 treatment days. VIRTUE QA detected 97 of 98 scenarios at or above the clinical Warning thresholds. The single undetected scenario was a spot-size perturbation at the Warning boundary in the lowest-traffic energy range. No false Warning or Error flags occurred during the unperturbed null evaluation.

Model Coverage and Training Data Age threshold testing. A conservative synthetic worst-case analysis included 3,888 gamma evaluations across six plans and 18 beams. The results support a Model Coverage and Training Data Age Error threshold of 90, with a Warning threshold of 95 providing an additional margin. This was a bounding surrogate analysis rather than direct model testing under artificially reduced coverage.

Independent dose-calculation validation. The GPU-accelerated MCsquare implementation used by DupliQate was compared with both RayStation TPS and CPU MCsquare calculations across five representative disease sites. GPU-versus-TPS 2%/2 mm gamma pass rates ranged from 98.5% to 99.9%, and GPU-versus-CPU rates ranged from 99.3% to 100.0%. Testing also included target and organ-at-risk dose comparisons, dose-volume histograms, dose-distribution difference maps, and heterogeneous anatomy.

7.6 Overall Performance Conclusion

The combined evidence demonstrates that VIRTUE QA produces machine-delivery predictions consistent with log-file reconstructions and independent physical measurements across the evaluated clinical operating envelope. Controlled perturbation testing characterizes detection sensitivity and false-alert behavior, while continuous post-treatment verification provides ongoing comparison of predictions with actual deliveries. Performance findings support the conclusion that VIRTUE QA is as safe and as effective as the predicate device.

8. Predetermined Change Control Plan Summary

VIRTUE QA includes a Predetermined Change Control Plan (PCCP) governing two planned modification types. The PCCP defines the permitted changes, validation methods, implementation controls, user communications, and ongoing monitoring required before and after each modification.

8.1 Modification 1 — Daily Model Retraining

Modification and boundaries. The six machine-specific predictive models are updated once daily using accepted delivery data accumulated during prior clinical operation. Only model weight parameters change. Software functionality, prediction model count, neural network architecture and node structure, data-processing methods, user interface, intended use, clinical outputs, and workflow remain unchanged.

Validation and implementation. Each candidate model set undergoes held-out performance assessment, localized residual assessment, and testing against approved sequestered test-plan baselines. A candidate with no Model Flags may be activated. Warning-level results trigger another training attempt while attempts remain and may be activated with visible Model Flags only after the configured attempts are exhausted. Error-level candidate model sets are not activated, and the prior validated model set remains active. Each treatment machine is trained, validated, activated, and monitored independently.

Additional controls and monitoring. Patient-specific physical-output validation checks each predicted spot against the commissioned machine operating envelope. Model Coverage and Training Data Age scores identify insufficient or stale supporting data. Post-delivery comparison with actual machine records and rolling prediction-versus-delivery gamma monitoring provide continuing performance surveillance.

Performance requirements. Modification 1 must continue to meet the performance requirements in Section 7.4: dose-distribution agreement of at least 90% gamma at 2%/2 mm or at least 95% at 3%/3 mm with a dose threshold no greater than 10%; spot-position mean prediction error ± 2 standard deviations within 1 mm; spot-size mean percent error ± 2 standard deviations within 15%; beam-level monitor-unit mean prediction error ± 2 standard deviations within 1%; and predicted spots remaining within the commissioned treatment-machine operating envelope. Candidate model sets must also meet the predefined held-out, localized-residual, and sequestered test-plan acceptance criteria before activation.

User communication. A Model Health Report communicates the active model-set identifier, validation status, performance metrics, and any Model Flags. Active Model Flags propagate to affected patient reports. The clinical workflow requires review and acknowledgment or explicit sign-off confirmation for applicable flags and retains the associated audit trail.

8.2 Modification 2 — Additional Proton Therapy Vendor Platforms

Modification and boundaries. Support may be extended to the identified Varian ProBeam, IBA Proteus ONE and Proteus Plus, and Hitachi ProBeat platforms. Permitted changes are limited to vendor-specific input mapping and data integration, configuration of machine-specific physical limits and validation thresholds, and site-specific commissioning specifications. The six prediction models, neural network architecture, and node structure remain unchanged; Modification 2 does not add prediction models, input nodes, hidden-layer nodes, output nodes, or other model-architecture elements. The intended use, indications for use, clinical decision outputs, training methodology, user interface, and clinical workflow are maintained.

Verification and validation. Each vendor-specific implementation undergoes full verification and validation as a new minor device version before release. Testing includes physical-measurement validation, independent dose comparison, representative disease sites and vendor-specific operating ranges, and a minimum one-month parallel clinical performance evaluation. Training-dataset establishment requires at least 50 unique beams covering at least 70% of the site's clinical energy range and 60% of the treatment field area. The clinical evaluation requires at least 20 treatment days. The performance requirements in Section 7.4 apply to each implementation.

Each installed treatment machine subsequently completes a site-specific deployment and commissioning process, including machine characterization, data-interface verification, shadow-mode operation, model validation, reference-baseline establishment, site acceptance testing, user training, and authorization for clinical release.

User communication. Updated labeling, release notes, UDI information, and applicable training are provided before deployment of a vendor-specific release.

All modifications must meet the acceptance, validation, implementation, communication, and monitoring requirements defined in the authorized PCCP before clinical use.

9. Conclusion

Based on the comparison of intended use, technological characteristics, and performance data, VIRTUE QA is substantially equivalent to the predicate device myQA iON (K201798). Performance evaluation findings support the conclusion that VIRTUE QA is as safe and as effective as the predicate device.

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