Prowess Inc.
% Rachel Scarano
Regulatory Affairs Manager
1844 Clayton Road
CONCORD, CA 94520

December 15, 2023

Re: K231825
Trade/Device Name: Panther TPS
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical Charged-Particle Radiation Therapy System
Regulatory Class: Class II
Product Code: MUJ
Dated: July 24, 2023
Received: July 26, 2023

Dear Ms. Rachel Scarano:

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.

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a

change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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.

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,

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K231825

Device Name
Panther TPS

Indications for Use *(Describe)*
IMRT – the IMRT module provides treatment planning for intensity-modulated radiation therapy (IMRT) using external photon beams.

RealART – the RealART module is intended to provide online correction of the position and shape of the beam portals based on the images acquired on the treatment day when the patient is in the treatment position.

ProArc – the ProArc module is intended to support treatment planning by creating treatment plans for intensity-modulated arc radiation therapy.

Stereotactic – the Stereotactic module is intended to support highly advanced precision-targeted radiation planning.

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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PROWESS

K231825

November 6, 2023

510(k) SUMMARY

As required by 21 CFR Part 807.92

1. Submitter:

Prowess Inc.
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Concord, CA. 94520

Contact Person:

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Device Manufacturer:

Prowess Inc.
1844 Clayton Road
Concord, CA. 94520

2. Device Trade Name: Panther TPS

Classification Name: Medical charged-particle radiation therapy system (21 CFR § 892.5050), Class II

Establishment Reg. No.: 2939248

Common Name: Radiation Therapy Treatment Planning System

Product Code: MUJ

Predicate Devices:

Predicate:
Prowess Inc.'s Panther Stereotactic, K193459

3. Device Description

Panther TPS is a three-dimensional treatment planning system for external beam radiation. The software is intended to assist in the relative positioning of radiation therapy treatment devices by predicting the three-dimensional isodose distributions that would be delivered for a particular device setting. It includes computation, display, evaluation and output documentation of radiation dose estimates to be submitted for independent clinical review and judgment prior to use.

Panther TPS is a Microsoft Windows based treatment planning system that includes several modules, each of which has a specific function or series of functions.

This significant change associated with the release of this version is a platform change, adding support for Windows Server.

4. Intended Use

The purpose of Panther Treatment Planning System is to provide a complete program for radiation therapy treatment planning. This includes computation, display, evaluation, and output documentation of radiation dose estimations to be submitted for independent clinical review and judgment prior to use. The device provides data in the form of display, hardcopy prints and/or plots to guide a physician in selecting the optimum patient treatment plan. Prowess products are radiotherapy treatment planning programs that allow radiation physicians, physicists, and dosimetrists to optimize the delivery of radiation in treating cancer and related diseases.

The radiation therapy treatment planning system provides two-dimensional and three-dimensional planning software for external (photon and electron) treatments using linear accelerators and cobalt-60 beams. The software includes several optional modules which are licensed to users.

5. Indications for Use

IMRT – the IMRT module provides treatment planning for intensity-modulated radiation therapy (IMRT) using external photon beams.

RealART – the RealART module is intended to provide online correction of the position and shape of the beam portals based on the images acquired on the treatment day when the patient is in the treatment position.

ProArc – the ProArc module is intended to support treatment planning by creating treatment plans for intensity-modulated arc radiation therapy.

Stereotactic – the Stereotactic module is intended to support highly advanced precision-targeted radiation planning.

6. Summary of Comparisons to Predicate Devices

Panther TPS is substantially equivalent to predicate device, Panther Stereotactic (K193459) for the purposes of premarket clearance, as demonstrated and documented in this premarket notification submission. Panther TPS and the predicate support Microsoft Windows OS. In addition, the rationalization for substantial equivalence is further evidenced through discussion of similar technological characteristics between Panther TPS and the predicate, as well as test results, which prove that Panther TPS is as safe and effective as the predicate device.

Panther Treatment planning system	*Predicate:* ***Panther Stereotactic Planning System (K193459)***
1. General operating procedure a) Standard data for developing a treatment plan: CT/MR images, contours, treatment field parameters, prescription. Objective function. b) Manually or automatically specify treatment field	**1. General operating procedure** a) Standard data for developing a treatment plan: CT/MR images, contours, treatment field parameters, prescription. Objective function. b) Manually or automatically specify treatment field

parameters c) Evaluate dose distribution d) Export plans	parameters c) Evaluate dose distribution d) Export plans
2. Inverse planning optimization Dose volume based objective function: target and OARs dose volume limits	**2. Inverse planning optimization** Dose volume based objective function: target and OARs dose volume limits
3. Dose calculation Supported dose algorithms are: Fast photon Collapsed Cone	**3. Dose calculation** Supported dose algorithms are: Fast photon Collapsed Cone
4. Plan evaluation The plan is evaluated using quantitative statistical tools such: Dose distribution evaluation: DVH, isodose distribution, cross-sectional dose distributions, point-dose calculations Target evaluation: target coverage, biological indices	**4. Plan evaluation** The plan is evaluated using quantitative statistical tools such: Dose distribution evaluation: DVH, isodose distribution, cross-sectional dose distributions, point-dose calculations Target evaluation: target coverage, biological indices
5. Final results The system calculates the dose from the source locations. The dose is reviewed before the final acceptance.	**5. Final results** The system calculates the dose from the source locations. The dose is reviewed before the final acceptance.
6. Windows Operating System Microsoft Windows 10 Microsoft Windows Server 2022	**6. Windows Operating System** Microsoft Windows 7 Microsoft Windows 10

7. Summary of Technological Considerations

Panther TPS has many of the same technological characteristics as the predicate device. There is a limited amount of distinguishing factors when comparing Panther TPS to the predicate, and those features that are different do not affect safety or effectiveness.

8. Summary of Non-clinical Tests

A hazard analysis was conducted, and associated documentation is included in this submission. Methods for preventing and/or mitigating defined hazards have been included as well. Verification and validation of the software was performed in-house according to established test plans and protocol. In addition, relevant regression testing was conducted by Prowess Quality Assurance to ensure that changes to the software did not result in any unanticipated, negative impact on other areas of the software. Verification and validation testing has demonstrated substantially equivalent performance to the predicate device's functions as intended and is safe and effective as compared to the predicate.

9. Performance Testing

Identical methods of performance testing were used on both the device and the predicate. Identical validation test cases were performed on both the device and the predicate, which demonstrates substantial equivalence and proves that no new issues of safety and effectiveness have been introduced.

10. Labeling

The CD media labeling, Instructions for Use and Panther TPS User Manual have been included. The User Manual, in digital format, is also included in the software media and can be viewed as part of the on-line help.

Product labels comply with 21 CFR 1040.10 and 1040.11 as applicable. In addition, labeling complies with applicable requirements of 21 CFR 801, including the requirement that the device be provided with adequate directions for use.

11. Summary of Safety and Effectiveness Information

a. Prowess, Inc. is a registered medical device establishment, whose quality system meets the requirements of ISO 13485 and FDA's QSR, 21 CFR 820.

b. Panther TPS was designed and implemented according to established Prowess Inc. established design and development, as well as quality management, procedures of Prowess Inc. In addition, design and development of the medical device software complies with internationally recognized standards including ISO 14971 *Medical devices – Application of risk management to medical devices,* IEC 62304 *Medical device software – Software life cycle processes,* and IEC 62083 *Medical electrical equipment – Requirements for the safety of radiotherapy treatment planning systems.*

c. The management of the company is committed to the highest standards of quality management. The Quality Management System is subject to regular, planned and documented audits by external consultants and by the FDA.

d. A comprehensive risk analysis has been conducted. Detailed methods of mitigating these potential risks have been identified by the development team, and verified by clinical physicists contracted by Prowess and determined to be adequate.

e. The software has been verified and validated based on established testing plans. The functionalities have been tested by in-house test engineers.

f. Directions and precautions for safe and effective use are included in the Instructions for Use and User Manual. Training by a Prowess specialist is also provided as part of product distribution/installation.

12. Level of Concern

As medical device software, the submission for Panther TPS follows FDA's G*uidance for the Content of Premarket Submissions for Software Contained in Medical Devices.* Since prior to mitigation of hazards, a failure of the software device could result in death or serious injury to a patient, it has been determined that the software correlates to a Major Level of Concern.

13. Conclusions

Panther TPS is substantially equivalent to the predicate device for the purposes of FDA clearance for commercial distribution. It has the same intended use and similar technical characteristics. The software has been found to perform as intended and the benefits to patient and user outweigh any inherent risks, which has been demonstrated via in-house testing as well as in field tests. Its use does not raise any new or different safety and effectiveness concerns when compared to the predicate.