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

April 27, 2020

Re: K193459
Trade/Device Name: Panther Stereotactic
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: Class II
Product Code: MUJ
Dated: December 11, 2019
Received: March 30, 2020

Dear Ms. 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 (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

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)*
K193459

Device Name
Panther Stereotactic

Indications for Use *(Describe)*
Panther Stereotactic 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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PROWESS

K193459

March 11, 2020

510(k) SUMMARY

As required by 21 CFR Part 807.92

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1. Submitter:

Prowess Inc.
1844 Clayton Road
Concord, CA. 94520

Contact Person:

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Device Manufacturer:

Prowess Inc.
1844 Clayton Road
Concord, CA. 94520

2. Device Trade Name: Panther Stereotactic

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

Product Code: MUJ

Establishment Reg. No.: 2939248

Common Name: Radiation Therapy Treatment Planning System

Predicate Devices:

Primary Predicate:
Elekta's Leksell GammaPlan, K173791
Additional Predicates:
American Radiosurgery, Inc.'s Explorer 4D Treatment Planning System, K101220
Prowess Inc.'s Panther ProArc, K101076

3. Device Description

Panther Stereotactic is an optional software module that has been added to the existing Prowess Panther Treatment Planning System to support planning with multiple shots instead of beams/arcs. Each shot is defined as a full or partial arc of one or multiple radiation sources with different collimator sizes depending on the machine configuration depending on the delivery types. Stereotactic forward planning extends Prowess Panther's existing arc definition features to define shot parameters such as location, size and arc angles. Stereotactic inverse planning extends Prowess Panther's existing simulated annealing algorithm to find optimal shot parameters such as location, size and arc angles.

4. Intended Use

Panther Stereotactic is intended to support highly advanced precision-targeted radiation planning.

5. Summary of Comparisons to Predicate Devices

Panther Stereotactic is substantially equivalent to primary predicate device, Elekta's Leksell GammaPlan (K173791), and additional predicate devices, American Radiosurgery, Inc.'s Explorer 4D Treatment Planning System (K101220) and Prowess Inc.'s Panther ProArc (K101076) for the purposes of premarket clearance, as demonstrated and documented in this premarket notification submission. In addition, the rationalization for substantial equivalence is further evidenced through discussion of similar technological characteristics between Panther Stereotactic and the predicates, as well as test results, which prove that Panther Stereotactic is as safe and effective as the predicate devices.

6. Summary of Technological Considerations

Panther Stereotactic has many of the same technological characteristics as the predicate device. There is a limited amount of distinguishing factors when comparing Panther Stereotactic to the predicate, and those features that are different do not affect safety or effectiveness. The dose calculation methods are slightly different, but have the same TMR based algorithm. In addition, Leksell GammaPlan runs on a Limun Operating System and Explorer 4D Treatment Planning System runs on Mac OS X, while Panther TPS runs on a Microsoft Windows OS. These are minor technical differences and do not affect substantial equivalence to the predicate devices.

7. Summary of Non-clinical Tests

A hazard analysis was conducted, and associated documentation has been included. Methods for preventing and/or mitigating defined hazards are detailed are detailed, and verification and validation of the software was performed in-house according to established test plans and protocol, which have been included as well. Functional testing was conducted both in-house and by OUR New Medical Technologies Ltd. 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 that Panther Stereotactic has met its predetermined specifications, demonstrated substantially equivalent performance to the predicate devices, functions as intended, and is safe and effective for its specified use.

8. Summary of User Site Testing

Although clinical testing is not required to demonstrate substantial equivalence in safety and effectiveness, we elected to conduct beta testing by OUR New Medical Technologies Ltd. to perform stereotactic planning under conditions equivalent to that of an actual clinical environment, in order to obtain feedback and to verify the results of in-house testing in a user environment. We feel that no matter how carefully a product is tested at the manufacturer's facility, such testing cannot replace actual use of the device in a clinical setting. As such, we consider both in-house testing and beta testing

at a user site during device development to verify safety and effectiveness, as well as to ensure that benefits to the patient from treatment with the device outweigh any inherent risks.

9. Labeling

The CD media labeling, Instructions for Use, Panther TPS User Manual, and marketing material all meet applicable regulations. 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.

10. Summary of Safety and Effectiveness Information

a. Prowess, Inc. is a registered medical device establishment, whose quality system meets the requirements of ISO 13485, Annex II of Medical Device Directive 93/42/EEC, and FDA's QSR, 21 CFR 820.

b. Panther Stereotactic 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 14971:2007 *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. In addition to in-house testing, the system was also tested by our beta-site using clinical cases. This testing has confirmed that the software is safe and effective in a clinical environment.

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.

11. Level of Concern

As medical device software, the submission for Panther Stereotactic 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, and as such, the associated documentation is included in this submission.

12. Conclusions

Panther Stereotactic is substantially equivalent to the predicate devices 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 predicates.