



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

September 28, 2021

Re: K211760
Trade/Device Name: Panther OIS
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: Class II
Product Code: IYE
Dated: June 4, 2021
Received: June 8, 2021

Dear 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 (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,

A handwritten signature in blue ink that reads "Michael D. O'Hara". The signature is written over a large, light blue "FDA" watermark.

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

Indications for Use

510(k) Number (if known)

K211760

Device Name

Panther OIS

Indications for Use (Describe)

Panther OIS is an information management system used to manage medical data and clinical workflow in a hospital or clinic. To support radiation oncology users, it allows the user to:

- Enter or import, modify, store and archive treatment plans and images from treatment planning systems.
- Import, view, manipulate, enhance, annotate, store, and archive radiological images.
- Select and provide radiation treatment plans to a radiation treatment delivery system for patient treatment.
- Store and view treatment records provided by the radiation treatment delivery system.

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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510(k) SUMMARY

As required by 21 CFR Part 807.92

K211760

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- 1. Submitter:** Prowess Inc.
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Concord, CA. 94520
- Contact Person:** Rachel Scarano
Regulatory Affairs Manager
Prowess, Inc.
1844 Clayton Road
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PHONE: (925) 356-0360
FAX: (925) 356-0363
Rachel.scarano@prowess.com
- Device Manufacturer:** Prowess Inc.
1844 Clayton Road
Concord, CA. 94520
- 2. Device Trade Name:** Panther OIS
- Classification Name:** Medical charged-particle radiation therapy system
(21 CFR § 892.5050), Class II
- Product Code:** IYE
- Establishment Reg. No.:** 2939248
- Common Name:** Oncology Information System
- Predicate Devices:** *Primary Predicate:*
Panther OIS|R&V, K122616
Additional Predicates:
Varian Medical Systems, Inc.'s ARIA, K173838
Elekta Solutions AB's MOSAIQ, K203172

3. Device Description

Panther OIS is an information management system used to organize medical data and facilitate the clinic workflow in a hospital or clinic. It is built on the Windows system as standard thin client-server system with a centralized database.

Panther OIS has incorporated and enhanced the previously cleared Prowess Panther OIS|R&V (K122616) into its framework so the user is able to:

- Record patient related information, especially radiation treatment planning and records.
- Schedule patients, medical resources and any type of activity.
- Capture procedure codes that will be used for billing.
- Generate reports for statistics purpose.
- Complete their tasks easily using the new ribbon UI that supports their workflow.
- Import treatment plans
- Record patient treatment histories
- Deliver treatment plans on radiation treatment delivery systems that have a DICOM interface for both external and stereotactic plans.
- Import, access, store and archive radiological images and review images to verify delivered treatment.
- The client is updated to a thin client so that it can be installed on more supported devices.
- Support for stereotactic treatment workflow which is similar to the external beam workflow but using a shot concept instead of a beam/arc concept.

Changes within the scope of this 510(k):

- Addition of support for stereotactic planning
- Addition of thin-client support, running resources stored on a central server instead of its localized hard drive
- R&V-related functionalities have been removed

4. Intended Use

Panther OIS is an information management system used to manage medical data and clinical workflow in a hospital or clinic. To support radiation oncology users, it allows the user to:

- Enter or import, modify, store and archive treatment plans and images from treatment planning systems.
- Import, view, manipulate, enhance, annotate, store and archive radiological images
- Select and provide radiation treatment plans to a radiation treatment delivery system for patient treatment.
- Store and view treatment records provided by the radiation treatment delivery system.

5. Summary of Comparisons to Predicate Devices

Panther OIS is substantially equivalent to primary predicate device, Prowess Panther OIS|R&V (K122616), and additional predicate devices, additional predicate devices, Varian's ARIA (K173838) and Elekta's MOSAIQ (K203172) 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 OIS and the predicates, as well as test results, which prove that Panther OIS is as safe and effective as the predicate devices.

OIS Feature	Panther OIS (Subject Device)	Panther OIS R&V (Primary Predicate, K122616)
Windows Operating System	Yes	Yes
Patient Chart/Record	Yes	Yes

OIS Feature	Panther OIS (Subject Device)	Panther OIS R&V (Primary Predicate, K122616)
DICOM Import	Yes	Yes
Export DICOM plan to treatment machines for plans containing beams/arcs/shots	Yes	Yes
Treatment Plans (Import, Store, Access, Modify, Archive)	Yes	Yes
Images (Import, Store, Access, Modify, Archive)	Yes	No
Image Review	Yes	No
Treatment machine Characterization	Yes	Yes
Scheduling	Yes	Yes
Activity Capture	Yes	No
Record & Verify (R&V)	No	Yes
Radiation Oncology	Yes	Yes
Medical Oncology	No	No
Support for Stereotactic Planning	Yes	No

6. Summary of Technological Considerations

Panther OIS has many of the same technological characteristics as the predicate device. There are a limited number of distinguishing factors when comparing Panther OIS to the predicate, and those features that are different do not affect safety or effectiveness. The main difference is that record and verify functions have been removed from the previously cleared device, which actually reduces the overall risk. 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, 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 United. 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 OIS 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 external testing by OUR United to verify safety and performance 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 DVD-ROM media labeling, Instructions for Use, Panther OIS 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 OIS 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 14971:2019 *Medical devices – Application of risk management to medical devices* and IEC 62304 *Medical device software – Software life cycle processes*.
- 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 an established testing plan. 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 OIS follows FDA's *Guidance 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 OIS is substantially equivalent to the predicate devices for the purposes of FDA clearance for commercial distribution. It has similar intended use and 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.