PROWESS

K101076

April 16, 2010

JUL 27 2010

510(k) SUMMARY

As required by 21 CFR Part 807.92

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 ProArc

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

Predicate Devices: (i) Varian Medical System's Eclipse Treatment Planning System with Arc beams (K073020)
(ii) Computerized Medical Solutions, Inc's Monaco RTP System – VMAT option (K091179)

3. **Device Description**

Panther ProArc is an optional software module to the Prowess Panther radiation therapy treatment planning system. It is an extension to the inverse planning, IMRT planning capability provided by Prowess Panther (previously cleared under K032456). Panther ProArc includes tools for visualizing and creating arc therapy plans, defining arc therapy beam properties and constraints, and allowing the user to do export these plans for delivery via DICOM protocol to the linear accelerator for treatment.

4. Intended Use

The Prowess Panther ProArc module is intended to support radiation treatment planning by creating treatment plans for intensity-modulated arc radiation therapy.

5. Summary of Comparisons to Predicate Devices

The Prowess Panther ProArc module is substantially equivalent to predicate devices, Eclipse Treatment Planning System with Arc beams (commonly referred to as "RapidArc") by Varian Medical Systems and the Monaco RTP System – VMAT Option from Computerized Medical systems, Inc. (which has since been acquired by Elekta), 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 ProArc and the predicates, as well as test results, which prove that Panther ProArc is as safe and effective as the predicates.

6. Summary of Technological Considerations

The Panther ProArc module has many of the same technological characteristics as the predicate devices. There is a limited amount of distinguishing factors when comparing Panther ProArc to the predicates, and those features that are different do not affect safety or effectiveness. This is described in detail in Section VII: Substantial Equivalence Comparison.

7. Summary of Non-clinical Tests

A hazard analysis was conducted, and associated documentation is included in Section VIII. Methods for preventing and/or mitigating defined hazards are detailed in Section IX: Software Verification & Validation. Verification and validation of the software was performed in-house according to established test plans and protocol, which have been included in Section IX as well. Functional testing was conducted both in-house and by medical physicists at Medical College of Wisconsin and Huntsman Cancer Hospital. 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 ProArc 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 at Medical College of Wisconsin and Huntsman Cancer Institute using real patient cases, 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, ProArc User Manual, and marketing material are provided in Section VI of this submission. 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, the Medical Device Directive 93/42/EEC Annex II and FDA's QSR, 21 CFR 820.

b. The Prowess Panther ProArc module 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. Documentation of these tests is included in Section IX of the submission.

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 the ProArc module of Prowess Panther Treatment Planning System 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 results 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

The Prowess Panther ProArc module is substantially equivalent to the predicate devices. 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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Ms. Rachel Scarano
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JUL 27 2010

Re: K101076
Trade/Device Name: Panther ProArc
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: MUJ
Dated: July 14, 2010
Received: July 16, 2010

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. 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.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donald J. St.Pierre
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

K101076

PROWESS

Tab 3

JUL 27 2010

Indications For Use

510(k) Number (if known): Pending

Device Name: Panther ProArc

Indications for Use:

The Prowess Panther ProArc module is intended to support radiation treatment planning by creating treatment plans for intensity-modulated arc radiation therapy.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, ~~Office of Device Evaluation (ODE)~~ OIVD

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

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