OCT 1 6 2003

K032452

510(K) SUMMARY

1.	**Submitter:**	Prowess, Inc. 1370 Ridgewood Drive, Suite 20 Chico, CA. 95973
	Contact Person:	W. James Bishop Regulatory /QA Manager Prowess, Inc. 1370 Ridgewood Drive, Suite 20 Chico, CA. 95973 PHONE: (530) 898-0660 FAX: (530) 898-0669
2.	**Device Manufacturer:**	Prowess, Inc. 1370 Ridgewood Drive, Suite 20 Chico, CA. 95973
3.	**Device Trade Name:**	Prowess Panther
4.	**Classification Name:**	Accelerator, Linear, Medical (21 CFR § 892.5050), Class II 90 MUJ
5.	**Reg. No.:**	2939248
6.	**Common Name:**	Radiation Therapy Treatment Planning System
7.	**Predicate Devices:**	Varian Eclipse, Helios option K021268 Nomos CORVUS Inverse Planning System K940663 ADAC P^3IMRT IMRT option K002237

8. Device Description

PROWESS PANTHER is an inverse planning option to the Prowess radiation therapy planning software for supporting intensity-modulated radiation therapy (IMRT) (K980379). The Prowess 3D system is composed of a Workstation with an Intel Pentium* processors (or later versions) running Windows 2000 operation system (or later versions) and proprietary software that allows the trained users to generate radiation therapy treatment plans.

The Prowess IMRT software contains 3 components:

1) **Objective and constraint specification** --- The first step of the inverse planning process is to allow the user to specify the treatment objectives,

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which include the dose and dose uniformity to the target or targets, the dose and volume limits to different critical organs, and the relative importance of achieving these objectives.

2) **Optimization** --- This is a process by which the system iteratively adjust the deliverable parameters including the field shapes and their weights to derive a treatment plan that best achieves the treatment objectives. A proven and most widely used optimization algorithm, simulated annealing, was used. As with P^{3}IMRT™ system by ADAC (K002237), IMRT uses the convolution superposition algorithm as the final dose calculation engine.

3) **DICOM Transfer** --- This involves transfer the plan parameters via DICOM-RT to a delivery control system (a Record and Verify system or the linear accelerator controller itself) for delivery.

9. Intended Use

Prowess Panther is an optional software module to the Prowess 3D™ Radiation Therapy Treatment Planning System. It is intended to provide treatment planning for intensity-modulated radiation therapy (IMRT) treatments using external photon beams.

10. Summary of Comparisons to Predicate Devices

There are many inverse planning systems for IMRT on the market. These predicate devices include the NOMOS CORVUS™ Inverse Treatment Planning System (K940663), Varian Eclipse, Helios Option (K021268) and the P^{3}IMRT™ system by ADAC (K002237). Prowess IMRT adds inverse planning capabilities to the existing Prowess 3D planning system (K980379). The entire system with the IMRT option incorporates no technical characteristics not currently contained in the predicate devices. It has the same intended use and the same optimization algorithm as the NOMOS CORVUS™ Inverse Treatment Planning System (K940663). As with P^{3}IMRT™ system by ADAC (K002237), Prowess Panther uses the convolution superposition algorithm as the dose calculation engine.

What distinguishes Prowess Panther from the predicate systems is described in detail under Section IV: Substantial Equivalence Comparisons. Our view, which is supported in the literature, is that aperture-based inverse planning such as the Direct Aperture Optimization (DAO) developed at the University of Maryland simplifies the planning and delivery process and makes IMRT less labor intensive and more reliable. Instead of a two-step process that first optimizes beam intensities and then convert the intensity distributions into deliverable parameters, DAO directly optimizes the deliverable parameters in one step. Since physical limitations of the linear accelerator and the multileaf collimator are

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considered in the optimization process, the actual delivered treatment more closely reflects the treatment plan.

11. Summary of Non-clinical Tests

A Hazard Analysis was completed for Prowess Panther. Methods for preventing such hazards were detailed (Section VII). Verification and validation of the software was conducted in house according to the Verification and Validation (V&V) Protocol. The V&V Protocol, and test results are included in Section VIII of this submission. Functional testing was conducted both in-house and by medical physicists/dosimetrists at the University of Maryland, School of Medicine. These tests have demonstrated that the Panther option to the Prowess 3D treatment planning system has met its specifications, demonstrated substantially equivalent performance to the predicate devices, and is safe and effective for its intended use.

12. Summary of Clinical Tests

Although clinical testing is not required to demonstrate substantial equivalence in safety and effectiveness, we elect to conduct testing at the University of Maryland Medical System using real patient cases. We feel that, no matter how carefully a product is tested in the factory, such testing cannot replace testing in the field. Clinical testing included commissioning machine data in the Prowess system, testing the dose calculation algorithm, transferring the patient images from a CT-Simulator, developing a treatment plan as described in the user manual, transferring the treatment plan to a linear accelerator and finally, delivering the plan to a phantom. The measured point doses showed agreement with calculated values within 3% for all the cases tested. This value surpasses the 5% specified in the guideline published by the American Society of Therapeutic Radiology and Oncology (ASTRO). The dose distributions captured by films showed that for high dose gradient regions, the distance to agreement is less than 2mm.

13. Labeling

TAB 6

The CD media labeling is provided in Section X and User's Manual are provided in Section VI of this submission. The entire user's manual in digital format is also included in the software media and can be viewed as part of the on-line help.

Commercial and marketing materials are also included in Section III.

Product labels comply with 21 CFR 1040.10 and 1040.11 as applicable.

14. Summary of Safety and Effectiveness Information

Summary of Safety and Effectiveness Information is included in Section VI as a free standing document. Only the contents of Section VI may be released by the

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FDA in satisfaction of Summary of Safety and Effectiveness Information requests as provided by SMDA 1990.

15. Conclusions

Prowess 3D's inverse planning option, Prowess Panther, is substantially equivalent to the predicate devices. It has the same intended use and similar technical characteristics. It generates equivalent quality of treatment plans as compared with the predicate devices as demonstrated in our field tests, and its use does not raise any new, or different issues of safety or effectiveness when compared with the predicates. As demonstrated in the comparison with predicate devices, the use of direct aperture optimization simplifies the planning and delivery of IMRT without sacrificing plan quality.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 16 2003

Mr. W. James Bishop
Regulatory/QA Manager
Prowess Inc.
1370 Ridgewood Drive, Suite 20
CHICO CA 95973

Re: K032456
Trade/Device Name: Prowess Panther
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: 90 MUJ
Dated: July 17, 2003
Received: August 16, 2003

Dear Mr. Bishop:

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 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

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 Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Tab 3

Indications For Use

510(k) Number (if known): Pending K032456

Device Name: Prowess Panther

Indications for Use:

Prowess 3D™ Radiation Therapy Treatment Planning System, including the IMRT option Panther™, is used to plan photon and electron radiation therapy treatments using linear accelerators and Cobalt-60 beams. The optional software module with the trade name Pather™ provides treatment planning for intensity-modulated radiation therapy (IMRT) treatments using external photon beams.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K032456