

MAY 18 1998

## 510(k) Summary of Safety and Effectiveness

The following Summary of Safety and Effectiveness is being submitted in conformance with 21 CFR 807.92.

K980379

1. **Contact Person / Submitter**

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2. **Device Name**

Classification Name: Radiation therapy treatment planning computer program  
Common/Usual Name: 3-D treatment planning system  
Proprietary Name: **Prowess Pro-Sim**

3. **Substantial Equivalence**

**Prowess Pro-Sim** is substantially equivalent to other legally marketed radiation therapy treatment planning systems currently in commercial distribution and previously determined to be substantially equivalent under section 510(k) including:

<b>Manufacturer</b>	<b>510(k) number</b>	<b>Device Name</b>
Nucletron	K921991	PLATO
Theratronics International Ltd.	K970236	Theraplan Plus
Picker International, Inc.	K923851	Picker Acquisim
ROCS	K862643	TPS 1031

A description of the operating principles and a detailed comparison of **Prowess Pro-Sim** to other legally marketed devices can be found in Appendix 2 of the 510(k) Submission.

#### 4. **Device Description**

The Prowess treatment-planning product is a series of independent software programs that are used to plan a course of radiation therapy. The treatment plan is an estimated dose distribution for a patient. The dose is computed by applying known and tested algorithms. Measured treatment machine data combined with geometric and tissue information, for a particular patient, are processed by the algorithm into a dose distribution.

The TPS software is designed to run on a personal computer (PC). Depending on the configuration of the program, the PC requires one of the following operating system: Windows NT, DOS or DOS under Windows-95. Other system components and peripherals include: 160 Mb of RAM, high resolution graphics display video card, network card, printer, plotter, digitizer, 3.5 inch floppy disk and tape backup drives.

#### 5. **Intended Use**

**Prowess Pro-Sim** is a modularly designed Radiation Treatment Planning Computer Program used to prepare individual treatment plans for cancer patients undergoing therapeutic radiation treatment. The system is utilized to develop treatment plans for Brachytherapy and External Beam (photon or electron) therapy. Completed treatment plans can be simulated using **Prowess Pro-Sim** in 3D on the computer's display prior to actual treatment.

**Prowess Pro-Sim** acquires CT and MR image data from a variety of DICOM compliant sources via its server module called **APEX**. MRI and CT machine data is acquired in a standard format from a variety of sources and stored in a database. **Prowess Pro-Sim** is used to contour and simulate radiation treatment therapy. Depending on the type of therapy, contouring information is passed from the **Prowess Pro-Sim** module to the **Prowess 500** module for Brachytherapy planning or the **Prowess 3000** module for External Beam planning. Once planning is complete, plans can be saved on the computer and printed using a variety of printers.

#### 6. **Summary of Technological Characteristics**

The Prowess Pro-Sim software can be run in several different configurations, depending on the users needs. Each major level of the configurations is listed below in order of increasing complexity. Each level of complexity will automatically include the previous levels and provide further capabilities and functions.

A utility program that is found in all configurations are a device testing program that is provided to perform hardware testing of any devices necessary to the film scanners, mouse, digitizing bit-pads, tape drives, printers and plotters to aid in diagnosing

hardware connectivity. Also global menu and security programs are provided to allow the user to enter the programs from the operating system as well as to provide and enforce secure methods to prevent unauthorized access to restricted devices, machine table data and patient sensitive information.

The P-500 series encompasses the brachytherapy planning functions of the software. The purpose of the program is to compute the radiation dose delivered for simple and complex treatment plans consisting of a multiple brachytherapy sources. The patient and plan information may be entered via the keyboard or digitizer, or imported from other file formats. Methods for entering sources and patient anatomy contours via pre-set templates, sliced film series and from shifted or rotated film sets are provided. The plans calculate the dose using a isotropic point source (1-D) or anisotropic line source (2-D) superposition of dose model. The doses may be computed at any point in 3D space, and may be visualized as 3-D dose sets. Statistical computations for plan adequacy as compared to specific anatomy and dose characteristic are also provided. Methods are also provided for printing and plotting the completed plan and patient model on hardcopy devices for later inclusion in the permanent patient record.

The P-1000 series includes subprogram to plan and compute the external beam, irregular fields, and simple daily calculation treatments along with the functionality of the P-500. The additional programs all use machine data that is entered, manipulated and stored in the machine database program.

The P-1000 Simple (Daily) Calculation product computes the radiation dose delivered for simple treatment plans consisting of a single beam of external radiation. Patient and plan information may be entered via the keyboard. The plans calculate the dose using a 1-D primary fluence and 1-D scatter model and provide a method for sending the data to a standard hardcopy device for later inclusion in the permanent patient record.

The P-1000 Prowess Irregular Fields computes the radiation dose delivered for simple treatment plans consisting of a single beam or two opposing beams of external beam radiation. Patient and plan information may be entered via the keyboard, augmented by a digitization method to enter block and collimator contours. The plans calculate the dose using a 2-D primary fluence and 2-D scatter model using data from the machine tables database. The results may be observed on the computer monitor and may be printed or plotted.

The P-1000 Prowess External Beam program is designed to allow the user to enter patient images or contours necessary to create radiotherapy treatment plans using external radiation, to enter treatment parameters and to compute the expected doses of radiation in the patient. It has the ability to use contoured from mouse or digitizer input and then store the information for later use. One transverse slice with multiple contours may be entered. Treatment plans in the form of beam geometry may be

applied and then calculated using a 3-D primary fluence and 1-D scatter model. The final results may be examined on the screen, and then may be printed or plotted.

The P-2000 Prowess External Beam program includes all of the functionality of the P-1000, and also allows the user to input more than one slice at a time of patient anatomy model data. Images may be imported directly onto the screen from film scanners using an image import utility program from several standard file formats. Contours must then be derived from the images using the mouse, digitizer or automatic contouring of well-defined anatomical regions. Window and level adjustments are available and provide enhanced visualization of an image when editing contours. Each slice may be calculated separately using the same algorithm as the P-1000 and the final results may be examined on the screen, and then may be printed or plotted.

The P-3000 Prowess External Beam program includes all of the functionality of the P-2000, and also allows the user to calculate, view and print all transverse slices in the patient model at the same time. The Apex version of this program expands the image import capability with the ability to transfer and convert DICOM 3.0 images into P-3000 format.

Pro-Sim VPS is a computed simulation program and may be used by itself or as a starting point for Prowess-3000. Pro-Sim VPS mimics the functionality of the standard x-ray treatment simulation in radiation therapy. In Pro-Sim VPS, images from the Apex transfer system may be imported and used to create a patient model. Contours and other identifying marks may be placed on the images from a 2D view, and a treatment plan may be generated using external beam machine data specified by the user and imported for use in Pro-Sim. The software generates a 3D view of the patient model using a digitally reconstructed radiograph that mimics the x-ray taken during the simulation step. The 2D and 3D information may be viewed from any direction, and may be printed or plotted to a hardcopy device. In addition, the images, contours, plans and beams may be exported to a Prowess-3000 compatible file for subsequent calculation of doses.

Lastly, FS2 is an additional film densitometry program that makes optical density measurements of film. It is not required for any of the other programs, and depending on the users needs, this option may be added to any of the above systems. The measurements may be exported to text files for later import into the machine database. Statistical summaries of film densities corresponding to common radiation therapy physics quality assurance techniques are also provided.

7. **Testing**

The **Prowess Pro-Sim** product was developed and tested according to a documented and signed plan. The plan provides details regarding the specific validation and verification protocols required to test the product. The Test plan, Verification and Validation protocols, example results, as well as a detailed summary of testing and results are provided as Appendix 5 of the 510(k) submission.

8. **Conclusion**

Documentation provided in the premarket notification shows in sufficient detail that the software development process was followed, that quality assurance procedures were adhered to, that testing demonstrates that the functional requirements were met, that the system meets its published specifications, and that the system performs as well as or better than the legally marketed devices specified in section 3 of this document.



MAY 18 1998

Food and Drug Administration  
9200 Corporate Boulevard  
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Thomas A. Boone  
Director of Regulatory Affairs and  
Quality Assurance  
Prowess Systems  
1370 Ridgewood Dr. Suite 20  
Chico, CA 95973

Re: K980379  
Prowess Pro-Sim System  
Dated: April 21, 1998  
Received: April 23, 1998  
Regulatory class: II  
21 CFR 892.5050/Procode: 90 IYE

Dear Mr. Boone:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,

Lillian Yin, Ph.D.  
Director, Division of Reproductive,  
Abdominal, Ear, Nose and Throat  
and Radiological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure



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**PREMARKET NOTIFICATION**

**Indications for Use Statement**

510(k) Number (if known) K980379

Device Name: **Prowess Pro-Sim**

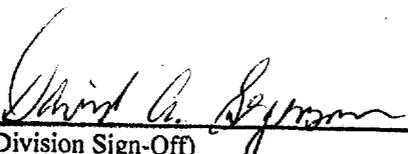
**Indications For Use;**

**Prowess Pro-Sim** is a modularly designed Radiation Treatment Planning Computer Program used to prepare individual treatment plans for cancer patients undergoing therapeutic radiation treatment. The system is utilized to develop treatment plans for Brachytherapy and External Beam (photon or electron) therapy. Completed treatment plans can be simulated using **Prowess Pro-Sim** in 3D on the computer's display prior to actual treatment.

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 Concurrence of CDRH, Office of Device Evaluation (ODE)

  
 (Division Sign-Off)  
 Division of Reproductive, Abdominal, ENT,  
 and Radiological Devices  
 510(k) Number K980379

Prescription Use   
 (Per 21 CFR 801.109)

OR

Over-the-Counter Use