



DEC 11 1998

Prowess Systems
 1370 Ridgewood Dr., Ste. 20
 Chico, California 95973
 Tel: (530) 898-0660
 Fax: (530) 342-8966

510(k) Summary of Safety and Effectiveness

- 1. Submitter:** **SSGI**
1370 Ridgewood Drive
Suite 20
Chico, CA 95973
- Contact:**
Robert J. Morton
Director, Regulatory Affairs
and Quality Assurance
- Prepared: November 16, 1998**
- 2. Device Name:** **Prowess Pro-Sim**
Radiation Therapy Treatment Planning System
- 3. Predicate Device:** **SSGI Prowess Pro-Sim, K980379**

- 4. Description:** The Prowess treatment-planning product is a series of independent software programs used to plan a course of radiation therapy. The treatment plan includes an estimated dose distribution for a patient. The dose is calculated 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 Prowess Treatment Planning System (TPS) is separated into three major components:

1. Incorporating patient data into a patient model.
2. Creating treatment plans for each set of patient data.
3. Calculating the treatment plans.

Pro-Sim TPS has all of the features of Pro-Sim VPS with the dose calculation capability of P3000. In this program the dose distribution can be shown in the 2D and 3D views.

- 5. Intended Use:** The Prowess Pro-Sim treatment planning system is used to plan patient treatment for radiation therapy.
- 6. Technological Characteristics:** See attached Comparison Table.



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Tab 15
Comparison to Unmodified Device

Prowess Treatment Planning System	Prowess Pro-Sim Predicate K0980379 Device	Prowess Pro-Sim TPS Modified Device
<u>Basic Features</u>		
Pro-Sim VPS has the ability to receive information from any manufacturer's CT scanner with DICOM 3.0 format on a network system. The Pro-Sim VPS computerized simulation process involves creation of a digitally reconstructed radiograph (DRR) in any plane desired. This appears on the computer screen for modification. The tumor volume is defined by adding multiple interior structure outlines to the transverse slices. In the beam's eye view, custom blocks and multileaf collimator blocking are accurately simulated by Pro-Sim VPS. These are superimposed on the grayscale DRR presented on the screen. Advanced tools for 3D visualization are transverse planes and wireframe contours surrounding 3D renderings of internal tumors and structures.	X	X
As the computer simulation is performed, the actual dose generated from the beams can be displayed in Pro-Sim TPS, change the beam or plan and watch the effect on the patient dosimetry, immediately.		X
<u>Basic System Design</u>		
• DICOM 3 compliant.	X	X
• Multilingual product design.	X	X
• Screen layout organized for rapid and consistent image display. Screen includes four display windows, a toolbar area, window and level graphic display, menu area and common function areas. All windows are active and have independent control.	X	X
<u>Image Acquisition</u>		
• DICOM 3 compliant Pro-Sim will accept CT images from any DICOM 3 image source.	X	X
• Ability to recall patients stored on any network station.	X	X
• Supports local area networks, wide area networks, or a distributed network through TCP/IP networking.	X	X
• At least 100 CT slices per study accepted.	X	X

Prowess Treatment Planning System

Prowess Predicate Device	Prowess Modified Device
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Image Processing and Anatomical Modeling

- | | | |
|---|---|---|
| • Rapid auto contouring includes multiple organ contouring using a Hounsfield number threshold technique. | X | X |
| • Easy entry of field shapes and calculation points. | X | X |
| • External and internal autocontouring. Batch autocontouring for multiplanar entry. | X | X |
| • Easy manual contouring and editing. | X | X |
| • Full mouse support. | X | X |
| • Easy to add margins on all volumes. | X | X |
| • Entry of calculation points for reference. | X | X |
| • Multiple calculation points available for a single field. | X | X |
| • Entry of fiducial points or isocenter marking to register patient anatomy. | X | X |

Full Three Dimensional Visualization of Treatment Setup

- | | | |
|--|---|---|
| • The treatment unit and patient anatomy can be visualized in three dimensions from any point in the treatment room. | X | X |
| • Direction of view can be dynamically moved in real time for full visualization of machine and patient. | X | X |
| • Anatomical features can be turned on and off easily. | X | X |
| • Full Zoom and Pan in each window. | X | X |
| • Turn on and off each contour display. | X | X |
| • Choose from a set of predefined beam configurations (e.g., Four Field, AP/PA, etc...) | X | X |
| • Supports beam configured for any 'brand' accelerator gantry and/or table orientation. | X | X |
| • Full 3-D patient and beam geometry. | X | X |
| • Independent jaws fully supported. | X | X |
| • Full couch, collimator and gantry rotation supported. | X | X |
| • MLC supported. | X | X |

External Beam Dose Calculations

- | | | |
|--|---|---|
| • Photon and electron beams can be combined in a single plane. | X | X |
| • Photon calculation makes extensive use of measured TMR/TPR data. Two heterogeneity models available: | X | X |
| Effective Path Length | X | X |
| Batho Power Law | X | X |
| • Bolus, compensators, blocks, and/or wedges may be mixed freely. | X | X |
| • CT pixel/density correction available. | X | X |

Prowess Treatment Planning System	Prowess Predicate Device	Prowess Modified Device
• At least 20 active beams per plan may be entered. They may be fixed or rotational beams.	X	X
• Necessary to export for dose calculations	X	
• 2D scatter calculations available.	X	X
• Calculation matrix size up to 16,384 per slice.	X	X
• Calculation of machine setting for each field.	X	X
• Non-coplanar beam calculations.		X
• 3D dose display.		X
<u>Hardcopy</u>		
• Scaleable color PostScript™ or HPGL hardcopy of CT images with color isodose curves.	X	X
• Pro-Sim hardcopy produces full color or black and white output on paper or film.	X	X
• Pro-Sim supports all printers supported by Windows NT.	X	X
• Full color hardcopy available.	X	X
• Dye sublimation printers (optional).	X	X
<u>Recommended Minimum Hardware Configuration</u>		
• Pentium® Pro or Pentium II workstation.	X	X
• Windows NT server or workstation operating system.	X	X
• 17" monitor.	X	X
• Screen resolution 1280 x 1024 pixels.	X	X
• 24-bit True Color display. CT or MRI images displayed using full 256 gray levels.	X	X
• Windows NT networking allowing multiple workstations for simultaneous simulation by physicians, physicists and dosimetrists.	X	X
<u>Export / Import Features</u>		
• All anatomical data including CT images can be exported to the Prowess 3000 RTP System using APEX™.	X	X
• All anatomical contouring data can be exported to the Prowess 3000 RTP system.	X	X
• Beam data generated by Pro-Sim can be exported to Prowess 3000 RTP.	X	X

Summary of Differences

Pro-Sim TPS is identical to Pro-Sim VPS, the predicate device with the exception that the dose calculations have been moved from Prowess 3000 into Pro-Sim VPS, creating Pro-Sim TPS. There is no longer a need to export the patient and beam geometry to Prowess 3000 to do the dose calculations. The calculation models are the same for both systems, Prowess 3000 and Pro-Sim TPS.

The comparison shows only two significant features that Pro-Sim TPS can do that the predicate system cannot do. First, Pro-Sim TPS can display the multi-slice dose calculation in 3D (there was no 3D view for dose calculations in the predicate device) and second, Pro-Sim TPS can do full non-coplanar beam calculations. The predicate device could perform dose calculations in all planes but could not combine them at one time due to machine interface limitations.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850Robert J. Morton
Director, Regulatory Affairs
and Quality Assurance
Prowess Systems
1370 Ridgewood Dr.
Suite 20
Chico, California 95973Re: K984196
Prowess Pro-Sim (Radiation Therapy Treatment
Planning System)
Dated: November 19, 1998
Received: November 23, 1998
Regulatory class: II
21 CFR 892.5050/Procode: 90 MUJ

Dear Mr. Morton:

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

Tab 9

Indications For Use

510(k) Number (if known): _____

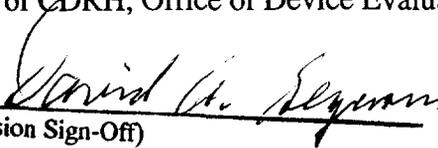
Device Name: Prowess Pro-Sim Treatment Planning System

Indications for Use:

Prowess Pro-Sim is a modularly designed radiation therapy 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 displayed in 3D prior to treatment.

(PLEASE DO NOT WRITE BELOW THIS LINE)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices

510(k) Number K984196

Prescription Use
(per 21 CFR 801.109)

OR

Over-The-Counter Use