

K992864

SEP 9 1999

SUMMARY OF SAFETY & EFFECTIVENESS

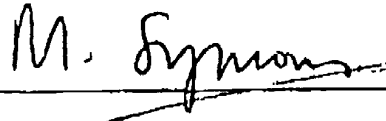
Precision Therapy International Inc. (PTI) hereby provides the following material summarising safety and effectiveness information for PTI Render-Plan 3-D*. This information is summarised as follows:

- 1) The Render-Plan 3-D* is an enhancement to the Render-Plan 3-D* (Formerly known as Renner-Plan) which has previously been cleared for commercial distribution (K894722 1/3/1990). This enhancement to Render-Plan 3-D* does not raise additional types of safety or effectiveness considerations.
- 2) The accompanying documents provided for the user contain comprehensive information to ensure safe and effective use. Past experience with substantially equivalent predicate devices has shown our device to be safe and effective when used as directed by the accompanying documents provided for the user.
- 3) It is our opinion that the Render-Plan 3-D does not have technological characteristics that raise additional types of safety or effectiveness questions, and that we consider them an enhancement to the existing Render-Plan 3-D*.
- 4) The Render-Plan 3-D* is designed to bear the CE mark affirming compliance with all relevant European Directives in force, in particular the European Medical Device Directive. As a result of this, products may be sold freely without restriction throughout the entire European Union.
- 5) PTI is a registered medical device establishment of assessed capability against the requirements of ISO 9001 and the Medical Device Directive 93/42/EEC Annex II.
- 6) PTI Quality System has been established to satisfy the requirements of ISO 9001, the Medical Device Directive 93/42/EEC Annex II, and 21 CFR 820. PTI has developed the Render-Plan 3-D* using an established and documented Quality Management System.
- 7) In accordance with the above requirements, all parts of the Quality System are subject to periodic and systematic internal Quality Audits. These audits are performed by trained personnel not having direct responsibilities in the functions being audited.

REF: DRC140-2030-01	Summary of Safety & Effectiveness Information for the PTI Render-Plan 3-D*		
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- 8) PTI has conducted risk analysis on the Render-Plan 3-D* and has concluded that it does not introduce hazards that raise new types of safety or effectiveness considerations. After considering the Guidance for the Content of Pre-Market Notification Submissions of Medical Devices Containing Software PTI has concluded the level of concern appropriate to the device is "Major".
- 9) The Quality System is subject to regular, planned and documented quality system audits conducted by external auditors from BSI (UK Notified Body) and the FDA.

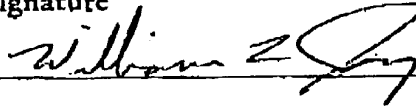
Signature



Mark Symons

President

Signature



William Joy

Quality Engineer

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SEP 9 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Paul L. Sumner
Director, Regulatory Affairs and Quality Assurance
Precision Therapy International
3155 Northwoods Parkway, NW
Norcross, GA 30071

Re: K992864
Render-Plan 3-D
Dated: August 25, 1999
Received: August 25, 1999
Regulatory Class: II
21 CFR 892.5050/Procode: 90 MUJ

Dear Mr. Sumner:

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 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). 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,

CAPT Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known):

Device Name: Render-Plan 3-D®

Indication for Use:

The Render-Plan 3-D® is intended to be used for planning the dosimetry of treatments in radiation therapy. It processes the inputs of the health care professional such that the desired radiation dose can be set on a radiation therapy delivery system.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

David A. Seymour
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices

(Optional Format 1-2-96)

510(k) Number K992864