

K970236

Summary of Safety and Effectiveness

Prepared: January 17, 1997 JUL - 9 1997

Submitter: Theratronics International Limited

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Contact: Mr. E. Martell
Vice President - Quality Assurance and Regulatory Affairs

Device: Trade Name: THERAPLAN Plus Version 1.2
Common Name: Radiation Therapy Treatment Planning System
Classification Name: Treatment Planning Computer

Predicate
Devices: Theratronics "THERAPLAN PLUS Version 1.0", K954679
Theratronics "THERAPLAN 500", K940237
Nucletron "PLATO", K921991
Radiation Oncology Computer Systems "TPS 1031", K862643
Precision Therapy "Render-Plan", K894722
ADAC "Pinnacle", K926008

Device Description:

THERAPLAN Plus Version 1.2 consists principally of application software running under a Windows operating system on a Pentium personal computer. Several THERAPLAN Plus Version 1.2 systems can be networked together for common access to pertinent data. The principal components of the THERAPLAN Plus Version 1.2 are listed below.

Hardware platform and Operating System: Pentium PC, Windows NT

Peripherals and accessories: Electromagnetic digitizer for manually entering patient anatomy, film scanner for entering anatomy from films, 9 track magnetic tape unit for

entering CT and MR images of patient anatomy, laser text printer, 300 dpi, 4 pages per minute minimum, colour printer, 300 dpi.

Main software features:

Unit Modelling of electron and photon beams from accelerators or Cobalt therapy units. Includes entry of wedges, blocks, and multileaf collimators.

Source Modelling of point sources, line sources and wires. The operator selects parameters for the sources which are required for treatment planning, such as size, isotope, wall thickness, and half-life.

Patient Data Acquisition by means of CT or MR images, a film scanner, or manually entered contours. CT or MR data may be acquired directly for units which support the DICOM 3 image format and communication standard, or by means of a software interface supplied by Theratronics for other units.

Anatomy Modelling to prepare the patient data for treatment planning. The portions of the anatomy which are of interest are selected, and contouring is performed of the anatomy exterior, the treatment target volume, and interior organs as needed for treatment planning.

Brachytherapy Planning may be performed using sources established during Source Modelling. The location of multiple sources may be specified and sample dose calculations performed. The location of sources may be adjusted for optimization. Time-domain calculations may also be performed based on the pattern of sources and their half-lives.

External Beam Planning may be performed using Unit Modelling data and Anatomy Modelling data. Electron and/or photon beams of different treatment units may be applied, and dose calculations performed. The location of the beams may then be adjusted for optimization. Arc therapy treatments can also be modeled.

The THERAPLAN Plus Version 1.2 also includes facilities for the operator to print the treatment plan information for review and to assist with the patient's treatment, and a compensator can be designed to help optimize the radiation pattern of an applied beam.

Intended Use:

THERAPLAN Plus Version 1.2 is intended to be used as a modelling system to assist health care professionals determine a course of Radiation Therapy to be delivered to a patient. The software is designed to run on a central host computer and support a number of peripherals and accessories. The system can be configured to enter scan data from

various types of CT scanners and MR scanners or to manually enter patient contour outlines. THERAPLAN Plus Version 1.2 systems can be networked together for common access to pertinent data.

THERAPLAN Plus Version 1.2 is intended to be used directly by a health care professional capable of assessing the suitability of the output for treatment planning purposes, or to have its output reviewed by someone with these qualifications prior to use.

Conclusion:

The THERAPLAN Plus Version 1.2 development and validation is in compliance with Theratronics product development procedures. These procedures ensure that system testing and validation demonstrate that the system meets its published specifications, performs as well or better than the predicate products to which is substantially equivalent, and is safe and effective for its intended use.

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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

E. S. Martell, Vice President
Quality Assurance and Regulatory Affairs
THERATRONICS International Limited
P.O. Box 13140
Kanata, Ontario
CANADA K2K 2B7

Re: K970236
THERAPLAN Plus Version 1.2 RTP System
Dated: April 29, 1997
Received: April 30, 1997
Regulatory Class: II
21 CFR 892.5050/Procode: 90 IYE

JUL - 9 1997

Dear Mr. Martell:

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 requirement, 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/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

Indications for Use

510(k) Number (if known): K970236

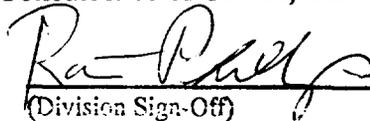
Device Name: THERAPLAN Plus Version 1.2 Radiation Therapy Treatment Planning System

Indications For Use:

THERAPLAN Plus Version 1.2 is intended to be used as a modelling system to assist health care professionals determine a course of Radiation Therapy to be delivered to a patient with cancer. It is designed to be used directly by a health care professional capable of assessing the suitability of the output for treatment planning purposes, or to have its output reviewed by someone with these qualifications prior to use.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



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

510(k) Number K970236

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)