JUN 2 5 2004

Pinnacle[3] Radiation Therapy Planning System version 7.2
510(k) Notification

K041577

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Submitters Name:	ADAC Laboratories, Inc.
Submitters Address:	6400 Enterprise Lane, Suite 201 Madison, WI 53719
Submitter Telephone:	(608) 288-6945
Submitter Fax:	(608) 298-2101
Contact Person:	Randy Vader Director, Quality & Regulatory
Date Summary Prepared:	May 3, 2004

Pinnacle^3 Radiation Therapy Planning System version 7.2
510(k) Notification

K041577

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Device Trade Name:	Pinnacle^3 Radiation Therapy Planning System
Common Name:	Radiation Therapy Planning System
Classification Name:	Accelerator, Linear, Medical (per 21CFR section 892.5050)
Predicate Devices:	Pinnacle^3 Radiation Therapy Planning System (K032724)

Device Description: Pinnacle^3 Radiation Therapy Planning System version 7.2 (hereafter Pinnacle^3 RTP) provides radiation therapy planning for the treatment of benign or malignant diseases. When using Pinnacle^3 RTP, qualified medical personnel may generate, review, verify, approve, print and export the radiation therapy plan prior to patient treatment. Pinnacle^3 RTP can provide plans for various radiation therapy modalities including External Beam Treatment, Stereotactic Radiosurgery, and Brachytherapy.

Pinnacle^3 RTP is a software package that runs on a Sun UNIX (or UNIX compliant) computer and consists of a core software module (Pinnacle^3) and optional software features. These optional software features, commonly referred to as "plug-ins", are typically distributed separate from the core software product (separate CD-ROM). The device has network capability to other Pinnacle^3 RTP workstations and to both input and output devices via local area network (LAN) or wide area network (WAN).

Image data is imported from CT, MR, PET, PET-CT and SPECT devices using a DICOM-compliant interface. A qualified medical professional uses the Pinnacle^3 RTP for functions such as viewing and analyzing the patient's anatomy, and generating a radiation therapy plan. The following are examples of tasks that may be performed by clinicians when using the Pinnacle^3 RTP system:

- Evaluate the treatment plan based on radiation-sensitive structures and the tumor.
- Combine both geometric and dosimetric planning on the same platform, including CT simulation data and plans. The CT simulation parts of the system are called AcQSim^3 and Simulation.
- Configure beam variables such as energy, geometry, and beam modifiers such as blocks, wedges, multi-leaf collimators, bolus and compensators.

Pinnacle^3 Radiation Therapy Planning System version 7.2
510(k) Notification

K041577

- Visualize the beam on a display, initiate the dose computation, and set the weight of each beam.
- Obtain dose measurements from any Points of Interest (POI).
- Perform photon and electron physics modeling, dose algorithm and machine commissioning. This functionality is supported by the Physics Utility Module.
- Evaluate images away from the workstation via a laptop or physician group workstation. The feature that provides remote review is referred to as P^{3}MD.
- Create data for use in conjunction with treatment QA systems.
- Configure, backup, archive, restore, and scripting.
- Evaluate Digitally Reconstructed Radiographs (DRRs) on Pinnacle^3 RTP or remote system using DICOM Secondary Capture (SC) Export.

Once complete, Pinnacle^3 RTP has the ability to transfer the finished plan to other devices used in the therapy process such as Record and Verify, Linear Accelerator (Linac) Workstations and/or 3rd Party QA systems.

The following Pinnacle^3 RTP features are also available to assist the clinician with the radiation therapy planning process. These features are distributed on standalone CD-ROM media, and installed onto the Pinnacle^3 RTP workstation. Corresponding instructions for use such as User Guides or Release Notes are also provided to the clinician for each optional feature.

P^{3}IMRT (Intensity Modulated Radiation Therapy):
P^{3}IMRT combines both forward and inverse planning functionality. The system determines a plan that satisfies the user's treatment goals through an optimization process. The user's treatment goals are specified as objectives and constraints based on dose distribution characteristics.

Syntegra (also referred to as AutoFusion):
Syntegra automates multi-modality image registration and fusion by overlaying images from CT, MR, PET, PET-CT and SPECT devices using a DICOM-compliant interface. This feature provides clinicians with the ability to relate, interpret and contour an image's anatomic and functional information.

In addition to the above, the following software options are available to facilitate image and/or data import and export between radiation therapy devices such as the imaging camera, Pinnacle^3 RTP, and Record &Verify system. DICOM is the acronym for Digital Imaging and Communications in Medicine and is an internationally recognized standard for transferring biomedical information such as images and data between devices or over a network.

Pinnacle^3 Radiation Therapy Planning System version 7.2
510(k) Notification

K041577

DICOM RT:
DICOM RT software is used to support both Structure Set and Radiation Therapy Plan import and export functions. Structure Sets describe regions and points of interest to other systems. Plan information includes beam geometry and delivery information.

DICOM Image:
DICOM Image software is used to support image import and export to and from the Pinnacle^3 RTP workstation according to the NEMA DICOM standard, version 3.0. This functionality allows diagnostic imaging devices supporting the DICOM 3.0 standard to interface with the Pinnacle system.

Mitsubishi DME:
A proprietary interface has been created within the Pinnacle^3 Treatment Planning System to support plan export to Mitsubishi Record and Verify systems. This interface is called the "Mitsubishi DME" system. This is implemented as a simple file based interface according to a format specified by Mitsubishi.

P^3 MD:
P^{3}MD allows for treatment plan review and minor alternations by a physician from a PC-based workstation that is connected to the same network as the primary Pinnacle^3 Treatment Planning workstation.

Indications for Use:
Pinnacle^3 Radiation Therapy Planning System is a computer software package intended to provide support for radiation therapy treatment planning for the treatment of benign or malignant disease processes.

Pinnacle^3 Radiation Therapy Planning System assists the clinician in formulating a treatment plan that maximizes the dose to the treatment volume while minimizing the dose to the surrounding normal tissues. The system is capable of operating in both the forward planning and inverse planning modes.

The device is indicated for use in patients deemed to be acceptable candidates for radiation treatment in the judgment of the clinician responsible for patient care.

Plans generated using this system are used in the determination of the course of a patient's radiation treatment. They are to be evaluated, modified and implemented by qualified medical personnel.

Pinnacle^3 Radiation Therapy Planning System version 7.2
510(k) Notification

K041579

Intended Use:
Pinnacle^3 Radiation Therapy Planning System version 7.2 provides support for dynamic multileaf collimator treatment planning.

Summary of Technological Characteristics Compared to Predicate Devices:
Pinnacle^3 Radiation Therapy Planning System version 7.2 makes two modifications to the existing Pinnacle^3 Radiation Therapy Planning System (K032724):

- The addition of support for dynamic multileaf collimator (DMLC) treatment planning. Dynamic multileaf collimator (also known as sliding window) is a technique in which the MLC leaves are continuously moving while the beam is on.
- The addition of improvements to the physics tool by updating the machine parameter definitions and enhancing the capabilities of the auto-modeling feature.

Pinnacle^3 Radiation Therapy Planning System version 7.2 incorporates no technological characteristics not currently contained in the predicate device: Pinnacle^3 Radiation Therapy Planning System (K032724). Pinnacle^3 RTP functionality is contained in one workstation.

Summary of Non-Clinical Tests:
A Hazard Analysis was completed for Pinnacle^3 Radiation Therapy Planning System version 7.2 and hazards were mitigated as appropriate. Verification and Validation test plans were completed in compliance with ADAC Laboratories procedures and will be utilized to demonstrate that the Pinnacle^3 Radiation Therapy Planning System version 7.2 has met its specifications, demonstrates substantially equivalent performance to the predicate device and is safe and effective for its intended use.

Summary of Clinical Tests:
Clinical testing is not required to demonstrate substantial equivalence or safety and effectiveness.

Conclusions:
Pinnacle^3 Radiation Therapy Planning System version 7.2 is substantially equivalent to the predicate device. It has the same intended use as the predicate device and its use does not raise any new or different issues of safety or effectiveness when compared to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 5 2004

ADAC Laboratories, Inc.
% Mr. William J. Sammons
Project Engineer
Underwriters Laboratories, Inc.
12 Laboratory Drive
Research Triangle Park, NC 27709

Re: K041577
Trade/Device Name: Pinnacle^3 Radiation Therapy Planning System Version 7.2
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: 90 LNH and MUJ
Dated: June 8, 2004
Received: June 14, 2004

Dear Mr. Sammons:

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 such 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

K041577

Pinnacle^3 Radiation Therapy Planning System version 7.2
510(k) Notification

INDICATIONS FOR USE

510(k) Number (if known):

Device Name: Pinnacle^3 Radiation Therapy Planning System version 7.2

Indications for Use:

Pinnacle^3 Radiation Therapy Planning System is a computer software package intended to provide support for radiation therapy treatment planning for the treatment of benign or malignant disease processes.

Pinnacle^3 Radiation Therapy Planning System assists the clinician in formulating a treatment plan that maximizes the dose to the treatment volume while minimizing the dose to the surrounding normal tissues. The system is capable of operating in both the forward planning and inverse planning modes.

The device is indicated for use in patients deemed to be acceptable candidates for radiation treatment in the judgment of the clinician responsible for patient care.

Plans generated using this system are used in the determination of the course of a patient's radiation treatment. They are to be evaluated, modified and implemented by qualified medical personnel.

Prescription Use ✓ OR Over-The-Counter-Use

(Per 21 CFR 801.109) (Optional Format 1-2-96)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lyman

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K041577