

APR - 7 2000

K993923

## 510(k) SUMMARY

**Device trade name:** Pinnacle<sup>3™</sup> Radiation Therapy Planning Software

**Common name:** Radiation Therapy Planning System

**Classification name:** Accelerator, Linear, Medical (per 21CFR section 892.5050)

**Predicate Devices:** Pinnacle<sup>3</sup> Apex Treatment Planning System, K951518  
ADAC Pinnacle<sup>3</sup> Software, K926008  
ACQPlan System, K974770

### Device Description:

Pinnacle<sup>3</sup> Radiation Treatment Planning Software is a system composed of a Sun Unix workstation running the Solaris operating system and software which provides the user with the capability to enter patient data into the system, use that data to construct a plan for radiation therapy, and evaluate the plan.

The system consists of a number of functional areas: physics, image import, image manipulation, contouring, point definition, photon and electron external beam treatment planning, stereotactic radiosurgery, brachytherapy, plan evaluation, file management and connectivity. Photons, electrons, stereotactic radiosurgery and brachytherapy functions are sold as separate options and may or may not be included in every system.

Pinnacle 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. Plans generated using this software 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.

### Intended Use:

Pinnacle<sup>3</sup> Radiation Therapy Planning System provides three-dimensional planning software for external beam (photons and electrons), stereotactic radiosurgery and brachytherapy planning.

### Summary of Technological Characteristics Compared to Predicate Devices:

Pinnacle<sup>3</sup> Radiation Therapy Planning Software has been designed to add new features and functions to the existing Pinnacle<sup>3</sup> Apex Treatment Planning System, cleared under K951518, in 1995. Pinnacle<sup>3</sup> Radiation Therapy Planning Software incorporates no technological characteristics not currently contained in the predicate devices, Pinnacle Apex System (K951518), ADAC Pinnacle<sup>3</sup> Software (K926008S2),

ACQPlan 3D RTP System (K974770), MMS TherPac PLUS (K982821), and I.M.S. Dose Calc. 1.02 (K990833).

**Summary of Non-clinical Tests**

Verification and Validation testing were completed in compliance with ADAC Laboratories procedures to demonstrate that the Pinnacle<sup>3</sup> Radiation Therapy Planning Software has met all its specifications, demonstrates substantially equivalent performance to its predicate devices, and is safe and effective for its intended use.

**Summary of Clinical Tests**

Clinical testing was not performed as part of the development of the device features described in this 510(k). Clinical testing is not required to demonstrate substantial equivalence or safety and effectiveness.



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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Janice E. Brown  
Corporate Director, Regulatory Affairs  
ADAC Laboratories  
540 Alder Drive  
Milipitas, CA 85035

Re: K993923  
Radiation Therapy Planning System (RTP)  
Dated: February 18, 2000  
Received: February 22, 2000  
Regulatory Class: II  
21 CFR 892.5050/Procode: 90 MUJ

Dear Ms. Brown:

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) 594-4591. 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 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,

Daniel G. Schultz, M.D.  
Captain, USPHS  
Director, Division of Reproductive,  
Abdominal, and Radiological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure(s)

510 (k) NUMBER (IF KNOWN): K993923

DEVICE NAME: Pinnacle<sup>3</sup> RTP Software

INDICATIONS FOR USE:

Pinnacle<sup>3</sup>™ Radiation Therapy Planning Software is a computer software package intended to provide support for radiation therapy treatment planning for the treatment of benign or malignant disease processes.

Pinnacle<sup>3</sup> Radiation Therapy Planning Software 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 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 software 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.

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

\_\_\_\_\_  
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X  
(Per 21 CFR 801.109)

OR

Over-The-Counter-Use \_\_\_\_\_  
(Optional Format 1-2-96)

David C. Johnson  
(Division Sign-Off)

Division of Reproductive, Abdominal, ENT,  
and Radiological Devices

510(k) Number K993923

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