

Advanced  
Radiation  
Therapy  
Systems, Inc.

430 Jean Way  
Advanced Radiation Therapy Systems, Inc., King of Prussia, PA 19406  
610-265-6519  
610-354-9226 (Fax)

K972816

JAN 23 1998

TAB 10

**Premarket Notification [510(k)] Summary**

July 25, 1997

Trade Name: Advanced Treatment Planning System

Common Name: Radiation Therapy Treatment Planning System

Classification Name: Medical charged particle radiation therapy system, 90 IYE (per 21 CFR section 892.5050)

Manufacturer's Name: Advanced Radiation Therapy Systems, Inc.

Address: 430 Jean Way  
King of Prussia, Pa 19406

Corresponding Official: Mr. Alexander C. Cheung

Title: Chief Executive Officer

Telephone: 610-265-6519 Fax: 610-354-9226

Predicate: Focus RTP: K915691 and Xknife-3: K953482

Device Description: The Advanced Treatment Planning System (ATPS) from Advanced Radiation Therapy Systems, Inc. (ARTS) is a software product that runs on a Silicon Graphics, Inc. UNIX Workstation in conjunction with specified accessory hardware. The ATPS provides the user the tools to easily perform patient treatment planning for the application of electron and photon radiation therapy utilizing input of patient anatomy from Computed Tomography (CT) and Magnetic Resonance Imaging (MRI) devices. Incorporation of 3D visualization software from Advanced Visualization Systems (AVS), combined with X windows and Motif graphics, results in a graphical user interface that is both flexible and easy to use. See the User's Manual in Tab 5 for a more detailed description and examples of graphics. The ATPS provides both two dimensional (2D) and three dimensional (3D) dose calculation algorithms for photons and electrons.

Intended Use: The Advanced Radiation Therapy Systems, Inc., "Advanced Treatment Planning System" is used to plan patient treatments for radiation therapy with external photons and electrons.

Technological Characteristics: See the attached "Predicate Comparison Table".

000417



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JAN 23 1998

Alexander C. Cheung  
Chief Executive Officer  
Advanced Radiation Therapy Systems, Inc.  
430 Jean Way  
King of Prussia, PA 19406

Re: K972816  
Radiation Therapy Treatment Planning System  
Dated: November 11, 1997  
Received: November 13, 1997  
Regulatory class: II  
21 CFR 892.5050/Procode: 90 IYE

Dear Mr. Cheung:

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 (Pre-market 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

TAB 11

510(k) Number (if Known) K972816

Device Name: Advanced Treatment Planning System

**Indications for Use:**

The Advanced Radiation Therapy Systems, Inc., "Advanced Treatment Planning System" is used to plan patient treatments for radiation therapy with external photons and electrons.

(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 B. Leggett  
(Division Sign-Off)  
Division of Reproductive, Abdominal, ENT,  
and Radiological Devices  
510(k) Number K972816

000413