

K090908

**Pinnacle³ Radiation Therapy Planning System SmartArc
510(k) Notification**

APR - 3 2009

510(k) SUMMARY

Submitters Name: Philips Medical Systems (Cleveland), Inc.

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Date Summary Prepared: December 19, 2008

Pinnacle³ Radiation Therapy Planning System SmartArc Module 510(k) Notification

510(k) SUMMARY

Device Trade Name:	Pinnacle ³ SmartArc
Common Name:	Radiation Therapy Planning System
Classification Name:	Accelerator, Linear, Medical (per 21CFR section 892.5050)
Predicate Devices:	Philips DMPO (K041577), Philips Conformal Arc (K041577), Elekta ERGO++ Version 1.7 (K080601), Varian Trilogy TM System with RapidArc (K072916)

Device Description:

The SmartArc module is an extension of P³IMRT that adds dynamic arc capabilities. A Dynamic Arc beam is similar to the current Conformal Arc beam but does not impose the restrictions of a constant dose rate or blocking a specific target.

The SmartArc solution utilizes continuous gantry motion in which the field shape defined by a multi-leaf collimator changes during gantry rotation. The dose rate can also be changed during rotation of the gantry.

Creation of a Dynamic Arc beam will be accomplished through a SmartArc optimization. The user will create a default Dynamic Arc beam, enter IMRT, assign objectives and perform a SmartArc optimization to provide an intensity Modulated Arc Treatment (IMAT) plan.

This extends the functionality of the Pinnacle³ Radiation Therapy Planning System (hereafter Pinnacle³ RTP) that provides radiation therapy planning for the treatment of benign or malignant diseases. When using Pinnacle³ RTP, qualified medical personnel may generate, review, verify, approve, print and export the radiation therapy plan prior to patient treatment. Pinnacle³ RTP can provide plans for various radiation therapy modalities including External Beam Treatment, Stereotactic Radiosurgery, and Brachytherapy.

Pinnacle³ RTP is a software package that runs on a Sun UNIX workstation and consists of a core software module (Pinnacle³) 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 Pinnacle³ RTP workstations and to both input and output devices via local area network (LAN) or wide area network (WAN).

This software automates multi-modality image registration and fusion by overlaying images from CT, MR, PET, PET-CT, and SPECT devices. This feature provides clinicians with the ability to relate, interpret and contour and image's anatomic and functional information.

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Image data is imported from CT, MR, PET, PET-CT and SPECT devices using a DICOM-compliant interface. A qualified medical professional uses the Pinnacle³ 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 Pinnacle³ 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 part of the system is called SmartSim.
- Configure beam variables such as energy, geometry, and beam modifiers such as blocks, wedges, multi-leaf collimators, bolus and compensators.
- 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.
- Create data for use in conjunction with treatment QA systems.
- Configure, backup, archive, restore, and scripting.
- Evaluate Digitally Reconstructed Radiographs (DRRs) on Pinnacle³ RTP or remote system using DICOM Secondary Capture (SC) Export.

Once complete, Pinnacle³ 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 Pinnacle³ 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 Pinnacle³ RTP workstation. Corresponding instructions for use such as User Guides or Release Notes are also provided to the clinician for each optional feature.

P³IMRT (Intensity Modulated Radiation Therapy):

P³IMRT combines both forward and inverse planning functionality for both static and dynamic treatments. 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.

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, Pinnacle³ 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.

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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 Pinnacle³ 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.

Indications for Use:

Pinnacle³ 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, using the dynamic multileaf collimator (DMLC) or “sliding window” technique.

Pinnacle³ 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.

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.

Intended Use:

SmartArc is a module for creating intensity modulated arc therapy plans.

Summary of Technological Characteristics Compared to Predicate Devices:

Pinnacle³ SmartArc makes modifications to the existing Pinnacle³ Radiation Therapy Planning System version 7.2 (K041577) that add support for treatment planning with Intensity Modulated Arc therapy (IMAT), using dynamic arc beams. A dynamic arc beam is a beam in which the gantry rotates about the patient and the Multi leaf Collimator (MLC) moves continuously, both while the beam is on. An optimization is done to determine the MLC positions as the gantry moves.

Documentation included in this 510(k) Premarket Notification supports the following modifications:

- Pinnacle³ RTP – introduces the ability to plan with Dynamic Arc Beams and characterize linear accelerators the are capable of delivering them.
- P³IMRT – adds the ability to optimize Dynamic Arc Beams within the IMRT module.
- DICOM RT – adds the support for the export of Dynamic Arc plans, associated dose grids and QA plans.

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Pinnacle³ SmartArc Module incorporates no technological characteristics not currently incorporated into the predicate device: Pinnacle³ Radiation Therapy Planning system version 7.2 (K041577).

For dose computation, the SmartArc Module uses the existing collapsed-Cone Convolution/Superposition (CCCS) algorithm that is currently used for photon dose computations, including Conformal Arc beams and for final dose computations in IMRT, including DMPO.

CCCS computes dose from first principles, taking into account the effects of beam modifiers, the patient shape and tissue heterogeneities on the dose distribution. It is based on the work by Mackie et al (see reference below). The model consists of four parts:

- Modeling the incident energy fluence as it exits the accelerator head.
- Projection of this energy fluence through the density representation of a patient to compute a TERMA (Total Energy Released per unit Mass) volume.
- A three-dimensional superposition of the TERMA with an energy deposition kernel using a ray tracing technique to incorporate the effects of heterogeneities on lateral scatter. The kernels are precomputed using a Monte Carlo technique.
- Electron contamination is modeled with an exponential falloff which is added to the dose distribution after the photon dose is computed.

During optimization for IMRT, DMPO or SmartArc, an iterative dose engine is used for increased speed. IMRT and DMPO use a pencil beam algorithm based on the existing CCCS model. SmartArc uses a Singular Value Decomposition (SVD) dose engine, similar to a pencil beam, as described by Bortfeld (see reference below). For any Pinnacle plan, final dose calculation must be done with the CCCS algorithm, due to its superior accuracy.

The ERGO++ Version 1.7 (K080601) solution uses a pencil beam algorithm. The TrilogyTM System with RapidArc (K072916) solution uses a modified pencil beam algorithm known as the Anisotropic Analytical Algorithm, or AAA, as described by Ulmer et al (see reference below). All such algorithms divide the treatment beam into small “pencils” or “beamlets”, compute dose separately for each and then sum them up to obtain the dose for the entire beam. Such methods do take patient geometry and tissue heterogeneities into account, but not as fully as a CCCS algorithm, particularly lateral to the beam direction.

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References:

T.R. Mackie, J.W. Scrimger, J.J. Battista, "A convolution method of calculating dose for 15-MV xrays," Med. Phys. 12, 188-196 (1985).

T. Bortfeld et al, "Decomposition of pencil beam kernels for fast dose calculations in three-dimensional treatment planning." Med. Phys. 20(2):pp. 311-318, 1993.

"A 3D photon superposition/convolution algorithm and its foundation on results of Monte Carlo calculations." W. Ulmer, J. Pyry, and W. Kaissl, Phys. Med. Biol. 50 (2005) 1767-1790

Summary of Non-Clinical Tests:

A Hazard Analysis was completed for Pinnacle³ Radiation Therapy Planning System SmartArc and hazards were mitigated as appropriate. Verification and Validation test plans were completed in compliance with Philips Medical Systems procedures and will be utilized to demonstrate that the Pinnacle³ Radiation Therapy Planning System SmartArc has met its specifications, demonstrates substantially equivalent performance to the predicate devices and is safe and effective for its intended use.

Summary of Clinical Tests:

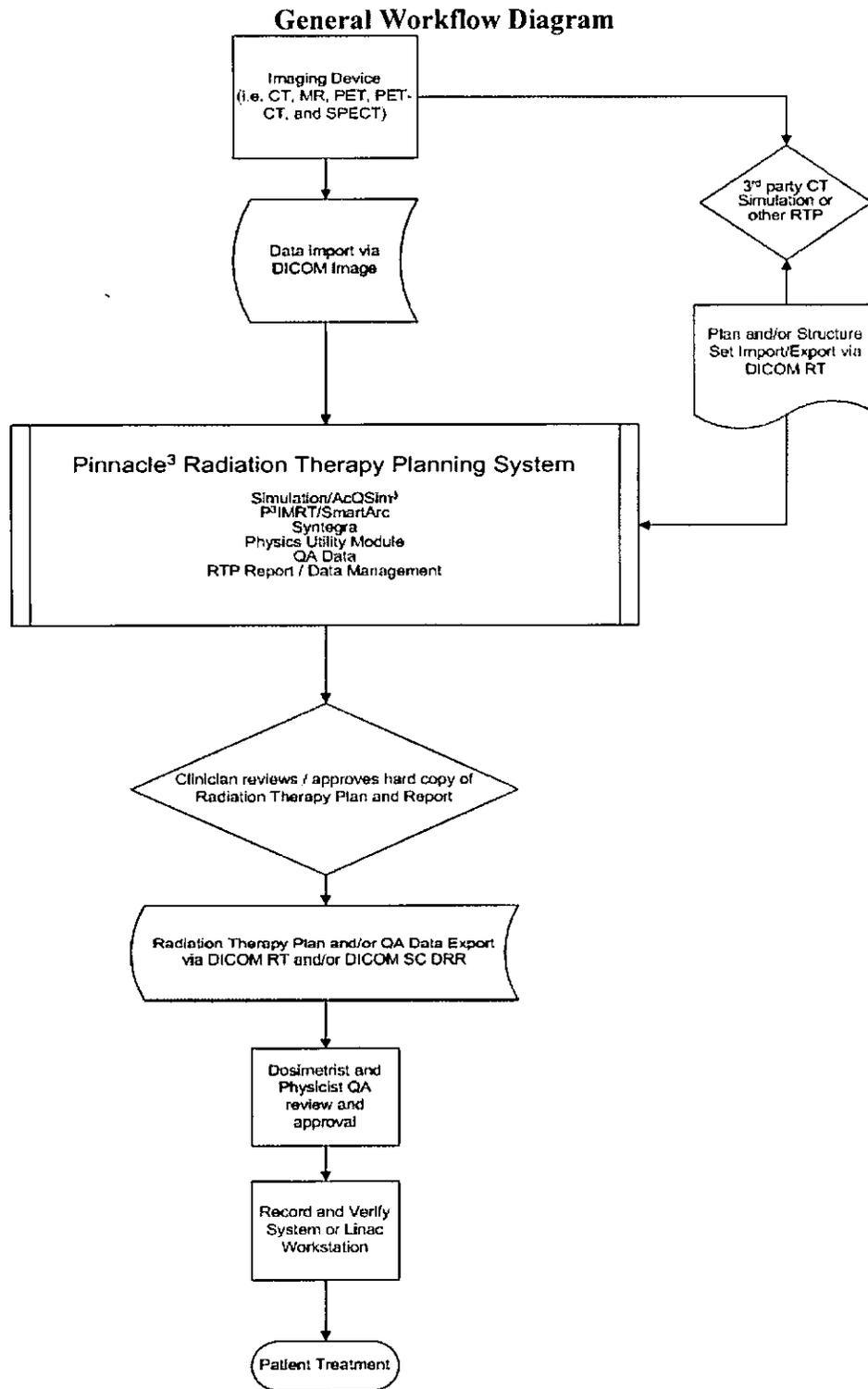
Clinical testing is not required to demonstrate substantial equivalence or safety and effectiveness.

Conclusions:

The Pinnacle³ Radiation Therapy Planning System SmartArc is substantially equivalent to the predicate devices. It has the same intended use as the predicate devices and its use does not raise any new or different issues of safety or effectiveness when compared to the predicate devices.

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Figure 1





Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Philips Medical Systems (Cleveland), Inc.
% Mr. Casey Conry
Senior Project Engineer
Underwriters Laboratories, Inc.
1285 Walt Whitman Rd.
MELVILLE NY 11747

APR - 3 2009

Re: K090808

Trade/Device Name: Pinnacle³ Radiation Therapy Planning System SmartArc Module
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: MUJ
Dated: March 23, 2009
Received: March 25, 2009

Dear Mr. Conry:

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.

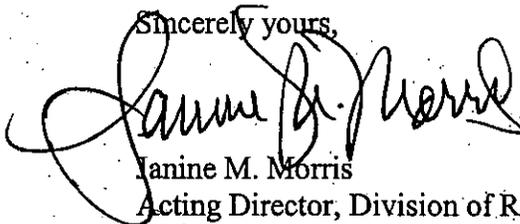
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to 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 this letter.

21 CFR 876.xxx	(Gastroenterology/Renal/Urology)	(240) 276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	(240) 276-0115
21 CFR 892.xxx	(Radiology)	(240) 276-0120
Other		(240) 276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry.suppot/index.html>.

Sincerely yours,



Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

**Pinnacle³ Radiation Therapy Planning System SmartArc
510(k) Notification**

INDICATIONS FOR USE

510(k) Number (if known): K090808

Device Name: Pinnacle³ Radiation Therapy Planning System SmartArc module

Indications for Use:

Pinnacle³ 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.

Pinnacle³ 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.

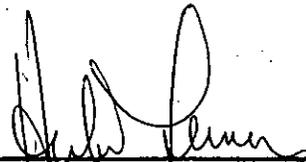
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of Reproductive, Abdominal and
Radiological Devices

510(k) Number

K090808