510(k) Summary

JUN 14 2013

1. Submission Sponsor

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3. Date Prepared

April 9th, 2013

4. Device Identification

Trade/Proprietary Name:	Philips Medical Systems (Cleveland), Inc.
Common/Usual Name:	Pinnacle³® Radiation Therapy Planning System
Classification Name:	Accelerator, Linear, Medical
Classification Regulation:	892.5050
Product Code:	MUJ
Device Class:	Class II
Classification Panel:	Radiology, RA90

5. Predicate Devices

K102216, Computerized Medical Systems, Inc., Xio RTP System – Proton Spot Scanning

6. Device Description

Pinnacle³® Radiation Therapy Planning System (hereafter Pinnacle³® RTP) provides radiation treatment 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, utilizing photon, proton, electron and brachytherapy techniques Stereotactic Radiosurgery, and Brachytherapy.

The Proton module builds on the Pinnacle³ Photon Treatment Planning Solution. A substantial part of the software architecture, display, connectivity and planning tools are transferable or extensible to the Proton Treatment Planning module. Using Pinnacle³® RTP as the base-line architecture will address the needs of operating and future treatment centers to seamlessly integrate photon with proton treatment planning.

Pinnacle³® RTP is a software package that runs on a Oracle Server and accessed through one or more clients, or an Oracle UNIX workstation and consists of a core software module (Pinnacle³) and optional software features (the Proton module requires the Oracle server and cannot be run on a workstation). These optional software features, commonly referred to as "plug-ins", are typically distributed separate from the core software product (separate CD or DVD). The device has network capability to other Pinnacle³® RTP workstations, thin client, 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 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 base features of 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. 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 values at 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.

In addition to the base Pinnacle[3®] RTP functionalities, Pinnacle Proton will provide the following:

Physics

- Define properties and parameter values for devices specific for passive double scattering and uniform scanning proton delivery techniques.
- Determine dose model parameter values and related functions, including Bragg Peak, Spread Out Bragg Peak, Effective SAD, Virtual SAD and Effective Source Size based on beam measurement data.
- Compute proton dose in a phantom and validate model implementation by comparing the computed profiles with the measured profiles for the same beam specifications, including Range, Modulation, Snout position, beam geometry, etc.
- Define parameters for beam modifier characteristics, including aperture and compensator specification. The parameters are material, stopping power, maximum and minimum physical thickness, milling specifications.
- Calibrate CT image data through the support of CT-Number to Stopping Power Tables for each CT scanner providing image data to be used for dose computation.
- Print a physics report containing machine and dose model information.

Planning

- Create a beam with a proton modality and determine clinical parameter values, including range, modulation and field size, based on a user-specified target.
- Generate beam dose computation parameters based on beam clinical parameters and a commissioned dose model.
- Provide a proton-specific compensator modifications using user-specified edge processing (border smoothing).
- Automatically generate beam apertures based on an assigned target, with the ability to specify a uniform margin and make manual edits to the aperture shape as desired.
- Provide the ability of overriding determined Stopping Power values in an image dataset, aiming to overcome artifacts in the planning CT image.
- Automatically determine target range and modulation, with the ability to determine set range and modulation through distal/proximal margin specification or manual entry.
- Generate setup DRRs at various commissioned imaging device positions.
- Detect a potential collision between the machine and the patient surface and support a variable snout position.
- Print a plan report containing proton beam specific information.

Once complete, Pinnacle[3®] RTP has the ability to transfer the finished plan to other devices used in the therapy process such as an OIS, Linear Accelerator (Linac) Workstations (as appropriate for photon) 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/DVD 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.

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*} RTP 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.

VCC: VCC 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 based on Oracle Virtual Desktop Client (OVDC) software.

P^{3}PDF: P^{3}PDF allows users to print to a .PDF file.

7. Indications for Use:

Pinnacle³® Radiation Therapy Planning System is a software package intended to provide planning support for the treatment of disease processes. Pinnacle³® Radiation Therapy Planning System incorporates a number of fully integrated subsystems, including Pinnacle³ Proton, which supports proton therapy planning. The full Pinnacle³® Radiation Therapy Planning System software package provides planning support for the treatment of disease processes, utilizing photon, proton, electron and brachytherapy techniques.

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 is 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.

8. Intended Use:

Pinnacle³® Radiation Therapy Planning (RTP) System is a software package intended to provide planning support for the treatment of disease processes, utilizing photon, proton, electron and brachytherapy techniques.

9. Substantial Equivalence Discussion

The following table compares the Pinnacle³® RTP system to the predicate device with respect to intended use, technological characteristics and principles of operation, providing more detailed information regarding the basis for the determination of substantial equivalence.

Table 5A – Comparison of Characteristics

Manufacturer	**Philips Medical Systems (Cleveland), Inc.**	**Computerized Medical Systems, Inc.**
Trade Name	Pinnacle³® RTP System	Xio RTP System – Proton Spot Scanning
510(k) Number	Not assigned	K102216 October 01, 2010
Product Code	MUJ	MUJ
Regulation Number	892.5050	892.5050
Regulation Name	Accelerator, Linear, Medical	Accelerator, Linear, Medical
Indications for Use	Pinnacle³® Radiation Therapy Planning System is a software package intended to provide planning support for the treatment of disease processes. Pinnacle³® Radiation Therapy Planning System incorporates a number of fully integrated subsystems, including Pinnacle³ Proton, which supports	The XiO Radiation Treatment Planning system accepts a) patient diagnostic imaging data from CT and MR scans, or from films, and b) "source"~ dosimetry data, typically from a linear accelerator. The system then permits the user to display and define (contour) the target volume, which is the

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	proton therapy planning. The full Pinnacle[3]® Radiation Therapy Planning System software package provides planning support for the treatment of disease processes, utilizing photon, proton, electron and brachytherapy techniques. 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. Plans generated using this system is 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.	structure to be treated, and critical structures, or organs-at risk, to which radiation dose must be limited. Based on the dose prescribed, the user, typically a Dosimetrist or Medical Physicist, can then create multiple treatment scenarios involving the type, number, position(s) and energy of radiation beams and the use of treatment aids between the source of radiation and the patient (wedges, blocks, ports, etc.). The XiO system produces a display of radiation dose distribution within the patient, indicating doses to the target volume and critical structures. Appropriate clinical personnel select the plan that they believe most effectively maximizes dose to the target volume while minimizing dose to critical structures. The parameters of the plan are output in hard-copy format for later reference placed in the patient file.
Intended Use	Pinnacle[3] Radiation Treatment Planning System is a software package intended to provide planning support for the treatment of disease processes, utilizing photon, proton, electron, and brachytherapy techniques.	The XiO RTP System is used to create treatment plans for any cancer patient for whom external beam radiation therapy or brachytherapy has been prescribed. The system will* calculate and display, both on-screen and in hard-copy, either two- or three-dimensional radiation dose distributions within a patient for a given treatment plan set-up.
Optimization Algorithm	No control point based optimization for the proton modality is supported (IMPT). Static, "3D conformal" delivery is supported only.	Full 3D optimization for Intensity Modulated Proton Therapy (IMPT) is supported as well as "3D conformal" therapy
Dose Engine: passive double scattering	Pencil beam algorithm based on the published work by: L. Hong *et al.*, "A pencil beam	Pencil beam algorithm based on the published work by: L. Hong *et al.*, "A pencil beam

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Trade Name	Pinnacle[3]® RTP System	Xio RTP System – Proton Spot Scanning
	algorithm for proton dose calculations,"Phys. Med. Biol. **41**, 1305–1330 (1996).	algorithm for proton dose calculations,"Phys. Med. Biol. **41**, 1305–1330 (1996).
Dose Engine: uniform scanning	Pencil beam algorithm based on the published work by: L. Hong *et al.*, "A pencil beam algorithm for proton dose calculations,"Phys. Med. Biol. **41**, 1305–1330 (1996).	Pencil beam algorithm based on the published work by: L. Hong *et al.*, "A pencil beam algorithm for proton dose calculations,"Phys. Med. Biol. **41**, 1305–1330 (1996).
Dose model parameter values and related functions	Measured data is imported and fitted to models based on published works for input into the dose engine: 1) A.Somov, D. Yeung, R. Slopsema, et.al, "Modeling and commissioning of a proton pencil beam algorithm at UFPTI" poster Particle Therapy Cooperative Group Annual Meeting 47, Jacksonville, FL, USA, May 19-24. 2) H. Szymanowski, A. Mazal, C. Nauraye, S. Biensan, R. Ferrand, M.C. Murillo, S. Caneva, G. Gaboriaud, and J.C. Rosenwald, "Experimental determination and verification of the parameters used in a proton pencil beam algorithm", Med. Phys. **28**, 975-987 (2001). 3) T. Bortfeld, "An analytical approximation of the Bragg curve for therapeutic proton beams", Med Phys. **24**, 2024-2033 (1997). *4)* Schaffner, B., Proton dose calculation based on in-air fluence measurements. *Phys. Med.Biol.*, **53**, 1545-62 (2008).	An interpolation method to shift and scale imported measured data to determine modeling parameter for input into the dose engine.
Vendor Independent	Yes	Yes
Beam modifier	Uses standard ray tracing and	Uses standard ray tracing and

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characteristics, including aperture and compensator specification	projection techniques Materials, limitations of size and thickness, physical milling techniques and limitations are all modeled	projection techniques Materials, limitations of size and thickness, physical milling techniques and limitations are all modeled
Export plan parameters required by DICOM-RT Ion standard	Yes	Yes
DICOM RT-Dose import and export	Yes	Yes
IMPT	No	Yes
Mixed Modality Planning	Yes. Dose is combined by summing up dose values from each modality in units of Co-60 equivalent Radiobiological Effective dose	No
Quality Assurance	Yes. Plan and physics reports, compensator and aperture printing, dose calculations in QA phantom, etc. are supported	Yes. Plan reports, compensator and aperture printing, dose calculations in QA phantom, etc. are supported
Beam Weight Optimization of Proton Beams	Simple point based method. No full 3D dose optimization performed—Monitor Units of pre-calculated, static beams adjusted only to meet point dose criteria.	unknown
Compensator Modification (Manual and Automatic)	Compensator thickness values are calculated from ray tracing techniques by determining difference in Water Equivalent Distance for each ray that intersect target for irradiation. The difference between the most distant ray and the individual ray represents the thickness of that compensator pixel. Physical milling techniques are incorporated to make software's representation of the compensator match real-world compensator result. User has manual and automated tools to adjust compensator. Manual tools based on user-desired thickness adjustments to one or more pixels of the compensator. Automated tools are based on	Compensator thickness values are calculated from ray tracing techniques by determining difference in Water Equivalent Distance for each ray that intersect target for irradiation. The difference between the most distant ray and the individual ray represents the thickness of that compensator pixel. Physical milling techniques are incorporated to make software's representation of the compensator match real-world compensator result. User has manual and automated tools to adjust compensator. Manual tools based on user-desired thickness adjustments to one or more pixels of the

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Trade Name	Pinnacle[3®] RTP System	Xio RTP System – Proton Spot Scanning
	published works: 1) M. Urie, M. Goitein, and M.Wagner. "Compensating for heterogeneities in proton radiation therapy." *Phys.Med.Biol,* **29**, 553-66 (1983)	compensator. Automated tools are based on published works: M. Urie, M. Goitein, and M.Wagner. "Compensating for heterogeneities in proton radiation therapy." *Phys.Med.Biol,* **29**, 553-66 (1983)
Anatomical Sites	Same, see below	Same, see below
Target Population	Same, see below	Same, see below
Standards Met and Performance	Same, see below	Same, see below

10. Non-Clinical Tests:

Verification tests were written and executed to ensure that the system is working as designed. Pass/fail requirements and results of this testing can be found in the Thunder Core Verification Test Report, which is included in section 16 of this submission. Pinnacle[3®] RTP successfully passed verification testing.

A Hazard Analysis was completed for Pinnacle[3®] RTP and hazards were mitigated as appropriate. Verification and Validation test plans were completed in compliance with Philips procedures and will be utilized to demonstrate that Pinnacle[3®] RTP has met its specifications, demonstrates substantially equivalent performance to the predicate device and that it does not raise different questions of safety and effectiveness as compared to the predicate device.

11. Clinical Tests:

Clinical trials were not performed as part of the development of this product. Clinical testing on patients is not advantageous in demonstrating substantial equivalence or safety and effectiveness of the device since testing can be performed such that no human subjects are e3xposed to risk. Algorithm testing was performed in a QA "Phantom" to compare calculated against measured doses to ensure dose calculation accuracy. In addition, clinical orientated validation test cases were written and executed by PMS customers at External evaluation sites with oversight by PMS customer support personnel.

12. Statement of Substantial Equivalence

It has been shown in this 510(k) submission that the difference between the Pinnacle[3®] RTP system and the predicate device do not raise any questions regarding its safety and effectiveness. The Pinnacle[3®] RTP, as designed and manufactured, is determined to be

substantially equivalent to the referenced predicate device.

13. Conclusions:

The Pinnacle³® RTP 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.

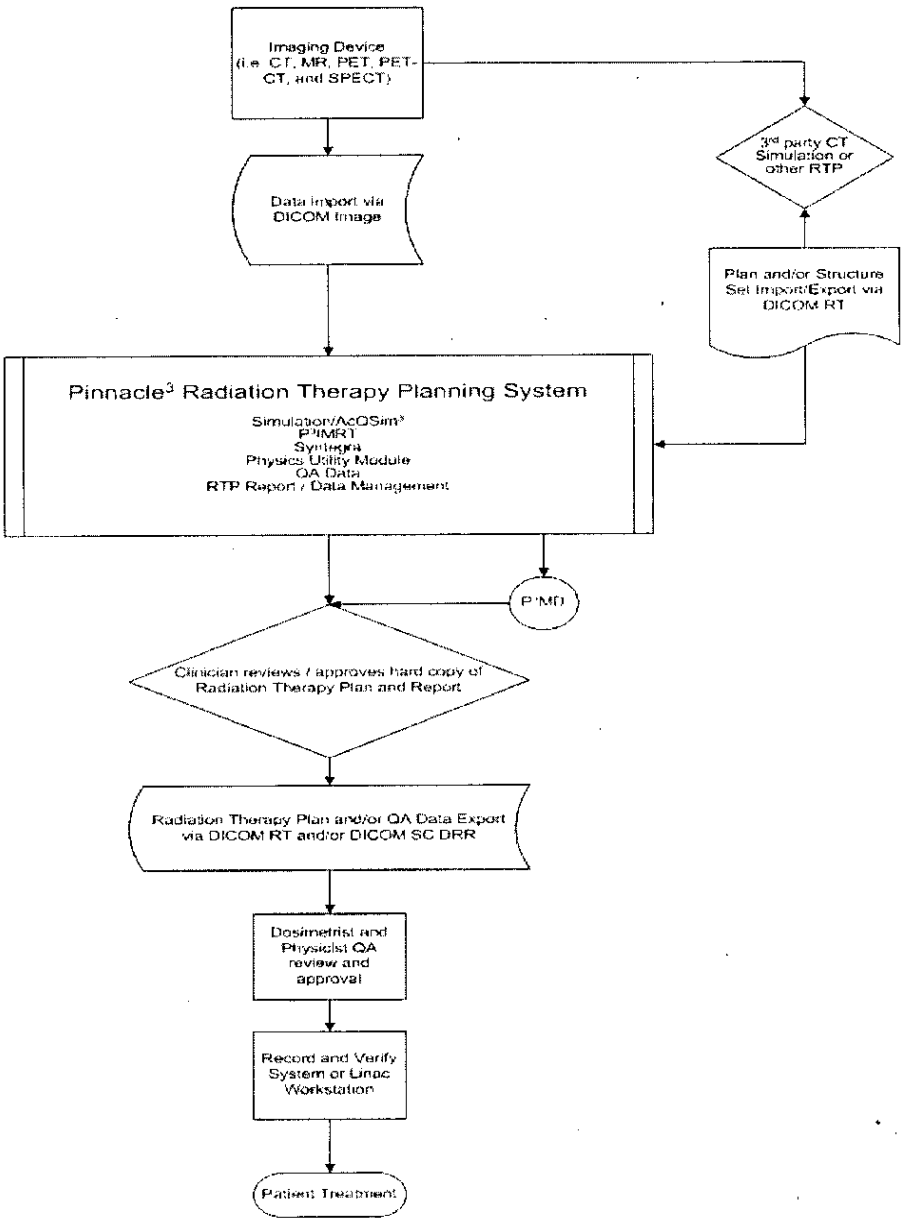

Figure 1 – General Workflow Diagram

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Philips Medical Systems (Cleveland), Inc.
% Ms. Diane Sudduth
Senior Consultant, QA
Emergo Group
816 Congress Avenue, Suite 1400
AUSTIN TX 78701

June 14, 2013

Re: K130992
Trade/Device Name: Pinnacle[3®] Radiation Therapy Planning System
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: April 9, 2013
Received: April 10, 2013

Dear Ms. Sudduth:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Michael D. O'Hara for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K130992

Device Name: Pinnacle$^{3®}$ Radiation Therapy Planning System

Indications for Use:

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Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

Michael D. O'Hara

(Division Sign Off)
Division of Radiological Health
Office of *In Vitro* Diagnostic and Radiological Health

510(k) K130992