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

February 9, 2017

Philips Medical Systems (Cleveland), Inc.
% Michelle Godin, MS, RAC
Sr. Manager, Regulatory Affairs
5520 Nobel Drive
FITCHBURG WI 53711

Re: K170086
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: MUJ
Dated: January 6, 2017
Received: January 10, 2017

Dear Ms. Godin:

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 Industry and Consumer Education 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" (21 CFR 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 Industry and Consumer Education 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,

For

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K170086

Device Name

Pinnacle3® Radiation Therapy Planning System

Indications for Use *(Describe)*

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.

Type of Use *(Select one or both, as applicable)*

☑ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

This 510(k) summary of safety and effectiveness information is prepared in accordance with 21 CFR 807.92.

Date Prepared: January 6, 2017

Manufacturer:
Philips Medical Systems (Cleveland), Inc.
5520 Nobel Drive
Fitchburg, WI 53711

Contact Person:
Michelle Godin, MS, RAC
Phone: 774.331.7499
Email: michelle.godin@philips.com

Device Name: Pinnacle[3®] Radiation Therapy Planning System
Software Release: Version 16.0

Classification:

Classification Name:	Accelerator, Linear, Medical
Classification:	21 CFR 892.5050
Regulation Classification Panel:	Radiology
Device Class:	II
Product Code:	MUJ

Predicate Device:

Trade Name:	Pinnacle[3®] Radiation Therapy Planning System
Manufacturer:	Philips Medical Systems (Cleveland), Inc.
510(k) Clearance:	K130992
Classification Name:	Accelerator, Linear, Medical
Classification:	21 CFR 892.5050
Regulation Classification Panel:	Radiology
Device Class:	II
Product Code:	MUJ

Device Description:

The Pinnacle[3®] Radiation Therapy Planning System (hereafter Pinnacle[3®] RTP System) provides radiation treatment planning for the treatment of benign or malignant diseases. When using the Pinnacle[3®] RTP System, qualified medical personnel may generate, review, verify, approve, print and export the radiation therapy plan prior to patient treatment. The Pinnacle[3®] RTP System can provide plans for various radiation therapy modalities including utilizing photon, proton, electron and brachytherapy techniques.

The Pinnacle[3®] RTP System is a software package that runs on an Oracle Server and is accessed through one (or more) client(s) or an Oracle UNIX workstation. The software package consists of a core software module

(Pinnacle^3) and optional software features, which are available through a licensing scheme. The device has network capability to other Pinnacle$^{3®}$ RTP System 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 Pinnacle$^{3®}$ RTP System 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 Pinnacle$^{3®}$ RTP system:

- Perform proton, photon, and electron physics modeling, dose algorithm and machine commissioning.
- 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, aperture 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).
- Evaluate Digitally Reconstructed Radiographs (DRRs) on Pinnacle$^{3®}$ RTP or remote system using DICOM Secondary Capture (SC) Export.

Once complete, the Pinnacle$^{3®}$ RTP System has the ability to transfer the finished plan to other devices used in the therapy process such as an Oncology Information System (OIS), Linear Accelerator (Linac), and/or 3rd Party QA systems.

The following optional Pinnacle$^{3®}$ RTP System features are available to assist the clinician with the radiation therapy planning process. These features are an integrated part of the Pinnacle$^{3®}$ RTP System and represent a subset of the optional features available to the user via licensing. Corresponding instructions for use such as User Guides or Release Notes are also provided to the clinician for each optional feature.

Pinnacle^3 Proton
Pinnacle^3 Proton provides support for Uniform Scanning and Double Scatter proton delivery devices. The system allows machine modeling and commissioning for machine definition. The system allows the user to utilize a commissioned machine for treatment planning purposes. The feature includes proton dose computation, and each beam is shaped using an aperture and a compensator.

Intensity Modulated Proton Therapy (IMPT):
IMPT provides support for Spot Scanning proton delivery devices. The system allows machine modeling and commissioning for machine definition. The system allows the user to utilize a commissioned machine for treatment planning purposes. The feature includes proton dose computation, and the beam dose is shaped by optimizing the relative weights applied to a spot pattern.

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.

Direct Machine Parameter Optimization (DMPO):
DMPO is a method of performing IMRT where Multi-Leaf Collimator (MLC) settings are produced directly within the optimization process.

Smart Arc:
SmartArc is a method of performing IMRT for linear accelerators that are capable of delivering intensity modulated arc treatments.

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.

Deformable Image Registration (DIR):
DIR provides the ability to create a Displacement Vector Field (DVF) based on a user-defined initial rigid registration between two CT images. DIR also introduces the tools that can be used to validate and approve the DVF, and the ability to apply the DVF to a CT image volume or a dose distribution.

Model-Based Segmentation (MBS):
MBS is library of individual organ models that provide a starting point for the contouring of individual Regions of Interest (ROIs).

Atlas Auto-Segmentation:
Atlas is a collection of organs models that are specific to an anatomical region and provide a starting point for Auto-segmentation of an image data set. Auto-segmentation uses an algorithm-based process that customizes the shape of each organ model into a set of ROIs that map to the patient anatomy.

Dynamic Planning:
Dynamic Planning provides the ability to transfer an entire treatment plan from one CT image to another. Also included is the ability to deform the ROIs from the original image to conform to the anatomy of the new image and the ability to store the ROIs and dose from the original plan in a read-only record that is viewable within the new plan.

Auto-Planning:
Auto-Planning automates a significant portion of the DMPO and SmartArc treatment planning process, providing major time and clinical efficiency gains to customers while also improving treatment plan quality and consistency. Auto-Planning includes the ability to customize, store, and apply templates that facilitate the planning and plan evaluation processes.

AcQSim^{3}:
AcQSim^{3} provides the tumor localization features that can be utilized at the time of scan acquisition or at the time of treatment. AcQSim^{3} is an integrated module that is accessible from within the Pinnacle^{3} planning application.

Tumor LOC:
Tumor LOC provides the tumor localization features that can be utilized at the time of scan acquisition. Tumor LOC is accessible directly from the console system connected to a CT scanner, and is remotely connected to the Pinnacle^{3} patient database.

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 System, 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 System 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$^{3®}$ RTP System.

Indications for Use:

The Indications for Use statement for the Pinnacle$^{3®}$ RTP System is as follows.

> Pinnacle$^{3®}$ Radiation Therapy Planning System is a software package intended to provide planning support for the treatment of disease processes. Pinnacle$^{3®}$ Radiation Therapy Planning System incorporates a number of fully integrated subsystems, including Pinnacle^{3} Proton, which supports 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.

Based on the information provided above, the Indications for Use of the Pinnacle$^{3®}$ Radiation Therapy Planning System remains unchanged from the predicate device (K130992, June 14, 2013), thus demonstrating substantial equivalence.

Fundamental Scientific Technology:

The Pinnacle$^{3®}$ RTP System provides radiation treatment planning support for the treatment of disease processes, utilizing photon, proton, electron, and brachytherapy techniques.

The Pinnacle^{3} Proton feature supports intensity-modulated treatment techniques on spot scanning delivery devices (Intensity Modulated Proton Therapy). The Intensity Modulated Proton Therapy (IMPT) features include physics modeling for spot scanning delivery, proton pencil beam dose computation, proton pencil beam optimization, robust analysis, and robust optimization. These features allow the user to create robust proton plans that take full advantage of spot scanning proton delivery techniques.

The Syntegra feature (the current image registration solution) now includes Deformable Image Registration (DIR). The DIR software supports the deformation of Computed Tomography (CT) image volumes and dose volumes. The DIR features include CT image deformation, dose deformation, and a variety of QA tools to evaluate the quality of the deformation. These features allow the user to evaluate a prior treatment against a new CT image to assist in the treatment decision process.

The IMPT features are conceptually similar to proton features in the predicate device, Pinnacle$^{3®}$ RTP System (Pinnacle^{3} Proton), with the main differences pertaining only to the modeling and planning features necessary to accommodate the machine characteristics. The features introduced with

DIR are a direct extension of existing functionality in the predicate device, Pinnacle[3®] RTP System (Syntegra).

Based on the information provided above, the Pinnacle[3®] RTP System is considered substantially equivalent to the predicate device (K130992, June 14, 2013) in terms of fundamental scientific technology.

Summary of Non-Clinical Performance Data:

The Pinnacle[3®] RTP System complies with the following international and FDA-recognized consensus standards:

- Consensus Standard IEC 62304 (Edition 1.0, 2006) – Medical Device Software – Software Life Cycle Processes.
- Consensus Standard ISO 14971 (2007, 2012) - Medical devices - Application of Risk Management to Medical Devices

Software verification testing has demonstrated that the IMPT and DIR features of the Pinnacle[3®] RTP System performs as intended in the specified use. The risk management activities show that all risks are sufficiently mitigated and that the overall residual risk is acceptable. No new concerns regarding safety or effectiveness have been raised by the introduction of the additional features to the Pinnacle[3®] RTP System.

Therefore, the Pinnacle[3®] RTP System is substantially equivalent to the predicate device (K130992, June 14, 2013) in terms of safety and effectiveness.

Summary of Clinical Performance Data:

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 exposed to risk. Verification testing was performed as required per the risk analyses and demonstrated that no new risks were introduced with the modifications in this submission.

Substantial Equivalence Conclusion:

The Pinnacle[3®] RTP System is substantially equivalent to the predicate device (K130992, June 14, 2013) in terms of design features, fundamental scientific technology, indications for use, and safety and effectiveness. A risk analysis was completed for the IMPT and DIR features of the proposed device, Pinnacle[3®] RTP System software version 16.0, and all hazards related to safety or effectiveness were mitigated as appropriate. Verification testing, specifically to address any safety or effectiveness concerns, was completed in compliance with Philips procedures and with the requirements specified in the international and FDA recognized consensus standards. The results of these tests demonstrate that the Pinnacle[3®] RTP System met the acceptance criteria and is adequate for its intended use.