Philips Medical Systems (Cleveland) Inc.
% Christine Anderson, B.S., RAC
Regulatory Affairs Specialist
595 Miner Road
CLEVELAND OH 44143

October 6, 2017

Re: K172406
Trade/Device Name: Ingenuity TF
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: II
Product Code: KPS and JAK
Dated: August 7, 2017
Received: August 9, 2017

Dear Ms. Anderson:

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 (DICE) 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 (DICE) 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,

Michael D. O'Hara 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)*
K172406

Device Name
Ingenuity TF

Indications for Use *(Describe)*
This device is a diagnostic imaging system for that combines Positron Emission Tomography (PET) and X-ray Computed Tomography (CT) systems. The CT subsystem produces cross-sectional images of the body by computer reconstruction of x-ray transmission data. The PET subsystem produces images of the distribution of PET radiopharmaceuticals in the patient body (specific radiopharmaceuticals are used for whole body, brain, heart and other organ imaging). CT data is applied to the PET data for attenuation correction. The PET subsystem also provides for list mode, dynamic, and gated acquisitions. This system is intended for patients of all ages.

Image processing and display workstations provide software applications to process, analyze, display, quantify and interpret medical images/data.
The PET and CT images may be registered and displayed in a "fused" (overlaid in the same spatial orientation) format to provide combined metabolic and anatomical data at different angles. Trained professionals use the images in:
• The evaluation, detection and diagnosis of lesions, disease and organ function such as but not limited to cancer, cardiovascular disease, and neurological disorders.
• The detection, localization, and staging of tumors and diagnosing cancer patients.
• Radiation therapy treatment planning and interventional radiology procedures.
The system includes software that provides a quantified analysis of regional cerebral activity from PET images.

Cardiac imaging software provides functionality for the quantification of cardiology images and data sets including but not limited to myocardial perfusion for the display of wall motion and quantification of left-ventricular function parameters from gated myocardial perfusion studies and for the 3D alignment of coronary artery images from CT coronary angiography onto the myocardium.

Both subsystems (PET and CT) can also be operated independently as fully functional, diagnostic imaging systems including application of the CT scanner as a radiation therapy simulation scanner.
This scanner is also intended to be used for diagnostic imaging and for low dose CT lung cancer screening for the early detection of lung nodules that may represent cancer*. The screening must be performed within the established inclusion criteria of programs / protocols that have been approved and published by either a governmental body or professional medical society.
*Please refer to clinical literature, including the results of the National Lung Screening Trial (N Engl J Med 2011; 365:395-409) and subsequent literature, for further information.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

PHILIPS

Philips Ingenuity TF
510(k) Summary

PHILIPS

510(k) Summary

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

Date Prepared:	August 4, 2017	
Manufacturer:	Philips Medical Systems (Cleveland), Inc. 595 Miner Road Cleveland, OH 44143, USA	
Primary Contact Person:	Christine Anderson Regulatory Affairs Specialist Phone: 440-483-3372 Fax: 440-483-2950 E-mail: christine.anderson@philips.cpm	
Secondary Contact Person:	Michael Preto Senior Manager, Regulatory Affairs Phone: 440-483-2295 Fax: 440-483-2950 E-mail: michael.preto@philips.com	
Device:	Trade Name:	Ingenuity TF
	Common name	Positron Emission Tomography, Computed Tomography X-Ray
	Classification Name:	System, Emission Computed Tomography/ System, Computed Tomography X-Ray
	Classification Regulation:	21 CFR 892.1200/ 21CFR 892.1750
	Classification Panel:	Radiology
	Device Class:	II
	Primary Product Code:	90 KPS (System, Emission Computed Tomography)
	Secondary Product Code:	90 JAK (Computed Tomography X-Ray)
Primary Predicate Device:	Trade Name:	Ingenuity TF
	Manufacturer:	Philips Medical Systems (Cleveland), Inc.
	510(k) Clearance:	K052640 (October 7, 2005, under name Gemini Raptor)
	Classification Name:	System, Emission Computed Tomography/ System, Computed Tomography X-Ray
	Classification Regulation:	21 CFR 892.1200/ 21CFR 892.1750
	Classification Panel:	Radiology
	Device Class:	II

PHILIPS

Product Code: 90 KPS (System, Emission Computed Tomography)
90 JAK (Computed Tomography X-Ray)

DEVICE DESCRIPTION:

The proposed Ingenuity TF is an integrated diagnostic imaging system that combines Positron Emission Tomography (PET) and X-ray Computed Tomography (CT). PET uses radiopharmaceuticals to obtain images by measuring the internal distribution of radioactivity within head, body and total body. PET technology enables the practitioner to reconstruct high-resolution, three-dimensional images of biochemical and metabolic processes of organs within the body. The Ingenuity TF utilized Time-of-Flight (ToF) technology for the PET reconstruction. CT is a medical imaging technique that uses X-rays to obtain cross-sectional images of the head or body. The system utilizes the CT technology to obtain anatomic images of the human body and PET technology to obtain functional images of the human body. The CT component can be utilized by clinicians for lung cancer screening. As such, lung cancer screening has been added to the Ingenuity TF intended use. The integration of the anatomical data from CT with the metabolic data from PET gives clinicians the visual information necessary to define the severity, as well as the extent, of the disease. The major subsystems of the PET/CT include the PET image reconstruction subsystem, the PET Data Acquisition subsystem, the CT Image reconstruction subsystem, the CT acquisition subsystem, the PET Gantry, the CT Gantry and the patient table. The system is suitable for all patients, infant through adult.

INTENDED USE:

This device is a diagnostic imaging system that combines Positron Emission Tomography (PET) and X-ray Computed Tomography (CT) systems. The CT subsystem produces cross-sectional images of the body by computer reconstruction of x-ray transmission data. The PET subsystem produces images of the distribution of PET radiopharmaceuticals in the patient body (specific radiopharmaceuticals are used for whole body, brain, heart and other organ imaging). CT data is applied to the PET data for attenuation correction. The PET subsystem also provides for list mode, dynamic, and gated acquisitions. This system is intended for patients of all ages.

Image processing and display workstations provide software applications to process, analyze, display, quantify and interpret medical images/data.

The PET and CT images may be registered and displayed in a “fused” (overlaid in the same spatial orientation) format to provide combined metabolic and anatomical data at different angles. Trained professionals use the images in:

• The evaluation, detection and diagnosis of lesions, disease and organ function such as but not limited to cancer, cardiovascular disease, and neurological disorders.

• The detection, localization, and staging of tumors and diagnosing cancer patients.

• Radiation therapy treatment planning and interventional radiology procedures.

The system includes software that provides a quantified analysis of regional cerebral activity from PET images.

Cardiac imaging software provides functionality for the quantification of cardiology images and data sets including but not limited to myocardial perfusion for the display of wall motion and quantification of left-ventricular function parameters from gated myocardial perfusion studies and for the 3D alignment of coronary artery images from CT coronary angiography onto the myocardium.

Both subsystems (PET and CT) can also be operated independently as fully functional, diagnostic imaging systems including application of the CT scanner as a radiation therapy simulation scanner.

This scanner is also intended to be used for diagnostic imaging and for low dose CT lung cancer screening for the early detection of lung nodules that may represent cancer*. The screening must be performed within the established inclusion criteria of programs / protocols that have been approved and published by either a governmental body or professional medical society.

*Please refer to clinical literature, including the results of the National Lung Screening Trial (N Engl J Med 2011; 365:395-409) and subsequent literature, for further information.

TECHNOLOGICAL CHARACTERISTICS:

The Ingenuity TF is substantially equivalent to the Gemini Raptor K052640 (marketed as Gemini TF) with regards to intended use, technological characteristics and safety and effectiveness. The proposed Ingenuity TF adds Lung Cancer Screening to the Indications for Use, which is not present in the predicate (Gemini Raptor K052640). Lung Cancer Screening was cleared by FDA for the Philips CT and PET/CT portfolio in K153444. This 510(k) will bring the indication under the Ingenuity CT system 510(k). The Ingenuity TF and the Gemini Raptor are substantially equivalent in regards to technological characteristics. Both the Ingenuity TF and the predicate, Gemini Raptor, have the same basic design, materials, energy sources, controls and software features. Both the Ingenuity TF and the predicate consist if a Positron Emission Tomography subsystem combined with a computed tomography x-ray subsystem. Both systems' PET detectors use LYSO based scintillation material, and have the same detector configuration. Both systems use radiopharmaceuticals to obtain images by measuring the internal distribution of radioactivity by the PET subsystem and fusing them with anatomic images of the human body taken by the CT subsystem. Both the Ingenuity TF and the predicate utilize ToF technology for PET reconstruction. The predicate had the option of a 6, 10, 16, 64 slice CT system. The Ingenuity TF has limited the CT to a 64 slice system with the option of 128 slices that are available through a license key.

Based on the information provided above, the Ingenuity TF is considered substantially equivalent to the primary currently marketed and predicate device Gemini Raptor in terms of fundamental scientific technology.

PHILIPS

SUMMARY OF NON-CLINICAL PERFORMACE:

Non-clinical performance testing was performed on the Ingenuity TF. Design Verification activities demonstrate the Ingenuity TF meets the established design input requirements. Design Verification also included Image Quality verification and risk analysis risk mitigation testing.

The Ingenuity TF complies with the FDA recognized consensus standards within the IEC 60601 series for basic safety, radiation protection, electromagnetic compatibility, usability, and particular x-ray equipment for computed tomography. Additionally, the Ingenuity TF was tested against NEMA NU 2:2012, Performance measurements of positron emission tomographs and ISO 10993-1:2009, Biological evaluations of medical devices – Part 1: Evaluation and testing with a risk management process. Testing was performed according to the following international and FDA recognized consensus standards:

- IEC 60601-1:2005+A1:2012 Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2:2007 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – requirements and tests
- IEC 60601-1-3 Ed. 2.0: 2008 Medical electrical equipment – Part 1-3: General requirements for basic safety – Collateral standard: Radiation protection in diagnostic X-ray equipment
- IEC 60601-1-6:2010 Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability
- IEC 60601-2-44:2009 Medical electrical equipment – Part 44: Particular requirements for the safety of X-ray equipment
- IEC 62304:2006 First edition medical device software – Software life cycle processes
- IEC 62366:2014 Ed1.1 Medical devices -- Part 1: Application of usability engineering to medical devices
- ISO 14971:2007 Medical devices – Application of risk management to medical devices

Design validation of user needs and intended use was conducted via simulated use testing with production equivalent Ingenuity TF Systems. Validation testing included clinical workflow validation and service validation.

Traceability from requirements to test plans to test results confirmed, for both design verification and design validation, that design requirements were met. The Ingenuity TF System meets system design requirements and user needs and intended use.

All these tests were used to support substantial equivalence of the subject device and demonstrate that the Ingenuity TF substantially equivalent to the predicate device Gemini Raptor in terms of safety and effectiveness.

SUMMARY OF CLINICAL PERFORMANCE:

PHILIPS

The Ingenuity TF did not require clinical study since substantial equivalence to the primary currently marketed and predicate device was demonstrated with the following attributes:

- Intended Use;
- Technological characteristics;
- Non-clinical performance testing; and
- Safety and effectiveness.

SUBSTANTIAL EQUIVALENCE CONCLUSION:

There was no change in Intended Use. The only change to indications for use was the addition of lung cancer screening which was cleared for the Philips portfolio under K1534444. Design Verification, Design Validation and performance tests demonstrate that Ingenuity TF complies with the requirements specified by Philips Medical Systems (Cleveland), Inc. and the international and FDA-recognized consensus standards and is as safe and effective as its predicate device without raising any new safety and/or effectiveness concerns.

The Ingenuity TF is substantially equivalent to the currently marketed predicate device Gemini TF (K052640 October 7, 2005, under name Gemini Raptor) in terms of intended use, technological characteristics and safety and effectiveness.