K123599
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Section 005

510(k) Summary

510(k) Summary in accordance with 21 CFR 807.92

Date:	20 November 2012
Submitter:	Philips Medical Systems (Cleveland), Inc. 595 Miner Road Cleveland, OH 44143 USA Establishment Registration: 1525965
Primary Contact Person:	Michael S. Preto Regulatory Affairs Specialist, CT/NM Regulatory Affairs Philips Medical Systems (Cleveland), Inc. Tel: +1 440 483 2295 Fax: +1 440 483 7355 E-mail: michael.preto@philips.com
Secondary Contact Person:	Melinda Novatny Senior Manager, CT/NM Regulatory Affairs Philips Medical Systems (Cleveland), Inc. Tel: +1 440 483 4255 Fax: +1 440 483 7355 E-mail: melinda.novatny@philips.com
Device Trade Name:	Ingenuity Digital PET/CT System
Common/Usual Name:	Combination PET/CT System
Classification Names:	Emission Computed Tomography System, 21 CFR 892.1200 X-ray Computed Tomography, 21 CFR 892.1750
Product Code:	90KPS 90JAK
Predicate Device(s):	K052640, Gemini Raptor
Device Description:	The device is a hybrid diagnostic imaging system that combines Positron Emission tomography and X-ray computed tomography scanners that can be utilized in fixed installations. The device is comprised of the following system components/subsystems: • Positron Emission Tomography (PET) scanner • X-ray Computed Tomography (CT) scanner • Patient Table • Acquisition and Control Workstations

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Intended Use:	The Philips Ingenuity Digital PET/CT System is a diagnostic imaging device that combines Positron Emission Tomography (PET) and X-ray Computed Tomography (CT) systems. The CT subsystem images anatomical cross-sections by computer reconstruction of x-ray transmission data. The PET subsystem images the distribution of PET anatomy-specific radiopharmaceuticals in the patient. The PET/CT system is used for the purpose of detecting, localizing, diagnosing, staging, re-staging and follow-up for monitoring therapy response of various diseases in oncology, cardiology and neurology. The system is intended to image the whole body, heart, brain, lung, gastrointestinal, bone, lymphatic, and other major organs for a wide range of patient types, sizes, and extent of diseases. Both subsystems can also be operated as fully functional, independent diagnostic tools including application of the CT scanner for diagnosis and for use in radiation therapy planning.
Technology:	The Ingenuity Digital PET/CT System has replaced the PET detector design and has integrated both PET and CT subsystems into a single gantry. The system operates on the same principles as the predicate device.
Determination of Substantial Equivalence:	The Ingenuity Digital PET/CT System has comparable indications for use as its predicate device. Summary of Nonclinical Tests: In accordance with "Guidance for the Submission of Premarket Notifications for Emission Computed Tomography Devices and Accessories (SPECT and PET) and Nuclear Tomography Systems ", system performance is provided using NEMA NU-2. Safety evidence is provided using IEC 60601 series of standards. Summary of Clinical Tests: In accordance with "Guidance for the Submission of Premarket Notifications for Emission Computed Tomography Devices and Accessories (SPECT and PET) and Nuclear Tomography Systems ", clinical images are included.
Conclusion:	Philips Medical Systems (Cleveland), Inc. considers the Ingenuity Digital PET/CT System to be as safe, as effective, and performance is substantially equivalent to the predicate device.

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

July 12, 2013

Philips Medical Systems (Cleveland), Inc.
% Mr. Michael S. Preto
Regulatory Affairs Specialist
595 Miner Road
CLEVELAND OH 44143

Re: K123599
Trade/Device Name: Ingenuity Digital PET/CT System
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: II
Product Code: KPS & JAK
Dated: June 6, 2013
Received: June 11, 2013

Dear Mr. Preto:

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 Form

510(k) Number (if known): K123599
Device Name: Ingenuity Digital PET/CT System
Indications for Use:

The Philips Ingenuity Digital PET/CT System is a diagnostic imaging device that combines Positron Emission Tomography (PET) and X-ray Computed Tomography (CT) systems. The CT subsystem images anatomical cross-sections by computer reconstruction of x-ray transmission data. The PET subsystem images the distribution of PET anatomy-specific radiopharmaceuticals in the patient. The PET/CT system is used for the purpose of detecting, localizing, diagnosing, staging, re-staging and follow-up for monitoring therapy response of various diseases in oncology, cardiology and neurology. The system is intended to image the whole body, heart, brain, lung, gastrointestinal, bone, lymphatic, and other major organs for a wide range of patient types, sizes, and extent of diseases. Both subsystems can also be operated as fully functional, independent diagnostic tools including application of the CT scanner for diagnosis and for use in radiation therapy planning.

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

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Michael D. O'Hara

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K123599