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 23, 2017

Philips Medical Systems Nederland B.V.
% Yoram Levy
General Manager
Qsite
31 Haavoda Street
Binyamina, 30500
ISRAEL

Re: K162484
Trade/Device Name: Lung Nodule Assessment and Comparison Option (LNA)
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ, JAK
Dated: January 15, 2017
Received: January 23, 2017

Dear Yoram Levy:

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)*
K162484

Device Name
Lung Nodule Assessment and Comparison Option (LNA)

Indications for Use *(Describe)*
The Lung Nodule Assessment and Comparison Option is intended for use as a diagnostic patient-imaging tool. It is intended for the review and analysis of thoracic CT images, providing quantitative and characterizing information about nodules in the lung in a single study, or over the time course of several thoracic studies. Characterizations include diameter, volume and volume over time. The system automatically performs the measurements, allowing lung nodules and measurements to be displayed.

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

510(k) Summary

K162484

Lung Nodule Assessment and Comparison Option

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

Date prepared: February 16, 2017

I. Submitter's name and address

Establishment name: Philips Medical Systems Nederland B.V.

Establishment address: Veenpluis 4-6
5684 PC Best
The Netherlands

Establishment registration: 3003768277

Primary Contact person: Yoram Levy, Qsite
QA/RA Consultant
31 Haavoda Street
Binyamina, Israel 30500
Tel +(972)4-638-8837;
Fax (972)4-638-0510
Yoram@qsitemed.com

Alternative contact person Mr. Yonel Braunstein
Head of Regulatory and Clinical Affairs
Philips Medical Systems Nederland B.V
E-mail: Yonel.Braunstein@philips.com

II. Device information

Trade name:	Lung Nodule Assessment and Comparison Option (LNA)
Device Classification Name	System, Image processing, Radiological
Device Class	Class II
Classification Panel	LLZ, JAK
Product Code	Radiological Image Processing Software
Regulation Description	21 CFR 892.2050, 21CFR 892.1750

PHILIPS

III. Predicate device information

Predicate devices:

Device trade name	510(k) number	Date of clearance	Classification name	Product code	Regulation	Class	Classification panel
Lung Analysis Software	K151283	October 30, 2015	System, Image processing, Radiological	JAK, LLZ	21CFR 892.1750	Class II	Radiology
Lung Nodule Assessment and	K023785	Feb 10 2003	System, Image processing, Radiological	90 JAK	21CFR 892.1750	Class II	Radiology

Reference devices:

Device trade name	510(k) number	Date of Clearance	Classification name	Product code	Regulation	Class	Classification panel
Philips Multi-slice CT system with Low Dose CT lung cancer screening	K153444	April 8, 2016	Computed Tomography X- ray system	JAK	21 CFR 892.1750	II	Radiology
Brilliance iCT (Brilliance Volume)	K060937	June 5, 2006	System, X-Ray, Tomography, Computed	JAK	21 CFR 892.1750	II	Radiology

I4 (Integrated Intelligent Imaging Informatics) system	K160315	February 19, 2016	Picture archiving and communication system	LLZ, JAK	21 CFR 892.2050	II	Radiology
EBW NM2.0	K111336	February 3, 2011	Picture archiving and communication system	LLZ	21 CFR 892.2050	II	Radiology

IV. Device description

The Lung Nodule Assessment and Comparison Option application is intended for use as a diagnostic patient-imaging tool. It is intended for the review and analysis of thoracic CT images, providing quantitative and characterizing information about nodules in the lung in a single study, or over the time course of several thoracic studies. The system automatically performs the measurements, allowing lung nodules and measurements to be displayed.
The user interface and automated tools help to determine growth patterns and compose comparative reviews. The Lung Nodule Assessment and Comparison Option application requires the user to identify a nodule and to determine the type of nodule in order to use the appropriate characterization tool. Lung Nodule Assessment and Comparison Option may be utilized in both diagnostic and screening evaluations supporting Low Dose CT Lung Cancer Screening*.

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

Key Features

1. Automatic Lungs and Lobes segmentation

2. Single-click lung nodule segmentation
3. Manual nodule segmentation editing tools
4. Load up to 8 concurrent studies for temporal measurements
5. Restore previously segmented nodules from prior studies for comparison
6. Enhanced comparison feature that allows matching and establishing correspondence between pre identified nodules in two studies
7. Synchronization between studies from different time-points
8. 3D or MIP visualization of segmented nodules
9. Reporting based on Lung-RADS™ guidelines and option to export to Clipboard
10. Risk Calculator tool based on patient and nodule characteristics for estimation of the probability that lung nodules detected on baseline screening low-dose CT scans are malignant, based on McWilliams, Annette, et al. "Probability of cancer in pulmonary nodules detected on first screening CT." New England Journal of Medicine 369.10 (2013): 910-919.
11. Automatic software calculation of the following measurements for each segmented nodule:

- Quantification of nodule parameters:
  - Long Axis- Longest diameter on an axial slice (mm)
  - Short axis- Longest diameter perpendicular to the long axis on the same slice (mm)
  - Average \ Max 3D \ Effective diameter (mm)
  - Volume (mm3)
  - Mean HU (HU)
- Manual edit of the nodule segmentation contour lines with automatic recalculation of geometric measurements post-editing
- Specification of the following characteristics for each nodule in configurable pre-sets
  - Nodule type (solid, part-solid, ground-glass, calcified)
  - Lobe Location
  - Nodule shape (Circular/Oval/Triangular)
  - Nodule Spiculation
- Comparison and matching feature automatic calculations of the following measurements between each follow-up scan and the previous scan:

- Doubling time in days
- Percent (%) and absolute change of all numerical parameters (growth in nodule long axis, short axis, average diameter, max 3D diameter, effective diameter, volume, mean HU).

Additional Information for Risk Calculator

The Risk Calculator feature in LNA is based on the full model with spiculation developed by Brock University as described in McWilliams, et al (2013). This model allows estimating the probability that lung nodules detected on baseline screening low-dose CT scans are malignant.

The model's performance was validated using two large population-based prospective studies: the Pan-Canadian Early Detection of Lung Cancer Study (PanCan) and the chemoprevention trials at the British Columbia Cancer Agency (BCCA), sponsored by the U.S. National Cancer Institute.

Further details can be found in *McWilliams, A., Tammemagi, M.C., Mayo, J.R., Roberts, H., Liu, G., Soghrati, K., Yasufuku, K., Martel, S., Laberge, F., Gingras, M. and Atkar-Khattra, S., (2013). Probability of cancer in pulmonary nodules detected on first screening CT. New England Journal of Medicine, 369(10), pp.910-919*

V. Intended use

The Philips Medical Systems Lung Nodule Assessment and Comparison Option is intended for use as a diagnostic patient-imaging tool.

It is intended for the review and analysis of thoracic CT images, providing quantitative and characterizing information about nodules in the lung in a single study, or over the time course of several thoracic studies. Characterizations include diameter, volume and volume over time. The system automatically performs the measurements, allowing lung nodules and measurements to be displayed.

PHILIPS

VI. Substantial Equivalence Comparison

Philips believes that Lung Nodule Assessment and Comparison Option product is substantially equivalent to the identified predicate devices , primary- Toshiba's Lung Analysis Software (K151283) and predicate- Philips' Lung Nodule Assessment and Comparison option (K023785), with additional/enhanced functionality deriving from the reference devices: Philips Multi-slice CT system with Low Dose CT lung cancer screening (K153444), Brilliance iCT (Brilliance Volume) (K060937), I4 (Integrated Intelligent Imaging Informatics) system (K160315) and EBW NM2.0 (K111336)

Below is the comparison table to summarize the similarities and differences of the subject, predicates, and reference devices:

Feature	The proposed device: Lung Nodule Assessment and Comparison Option (LNA application)	Primary Predicate: Toshiba's Lung Analysis Software (K151283)	Predicate: Philips' Lung Nodule Assessment and Comparison option (K023785)	Reference device
Device Classification Name	System, Image processing, Radiological	System, Image processing, Radiological	System, Image processing, Radiological	Not relevant for this subject
Device Class	Class II	Class II	Class II	Not relevant for this subject
Classification Panel	Radiology	Radiology	Radiology	Not relevant for this subject
Product Code	LLZ, JAK	JAK, LLZ	90 JAK	Not relevant for this subject
Regulation Description	Radiological Image Processing Software	Radiological Image Processing Software	Radiological Image Processing Software	Not relevant for this subject
Regulation Number	21 CFR 892.2050 21CFR 892.1750	21CFR 892.1750	21CFR 892.1750	Not relevant for this subject

PHILIPS

Indication For Use	The Lung Nodule Assessment and Comparison Option is intended for use as a diagnostic patient-imaging tool. It is intended for the review and analysis of thoracic CT images, providing quantitative and characterizing information about nodules in the lung in a single study, or over the time course of several thoracic studies. Characterizations include diameter, volume and volume over time. The system automatically performs the measurements, allowing lung nodules and measurements to be displayed.	The separately licensed Lung Analysis option is intended for the review and analysis of thoracic CT images for the purposes of characterizing nodules in the lung in a single study, or over the time course of several thoracic studies. Characterizations include diameter, volume and volume over time. The system automatically performs the measurements, allowing lung nodules and measurements to be displayed.	The Lung Nodule Assessment and Comparison Option is intended for use as a diagnostic patient-imaging tool. It is intended to provide quantitative information about physician-indicated lung nodules that are identified on high-resolution computed tomography images of the lung.	Not relevant for this subject
Intended users	Radiologists and Technologist	Radiologists, Technologist and Oncologists	Radiologists and Technologist	Not relevant for this subject
Intended body part	Chest	Chest	Chest	Not relevant for this subject
Type of scans	Thoracic CT images	Thoracic CT images	Thoracic CT images	Not relevant for this subject
2D image review	Yes	Yes	Yes	Not relevant for this subject
3D image review	Yes	Yes	Yes	Not relevant for this subject
2D and 3D comparative review	Yes	Yes	No	Not relevant for this subject

2D measurements	Yes	Yes	Yes	Not relevant for this subject
Segmentation of lung airway, lungs and lung lobes	Yes	Yes	No	Brilliance iCT (Brilliance Volume), (K060937)
Single click lung nodule segmentation	Yes	Yes	Yes	Not relevant for this subject
Nodule Characteristics	Yes	Yes	No	Not relevant for this subject
Automatic calculation of measurements for each segmented nodule	Yes ▪ Short axis- Longest diameter perpendicular to the long axis on the slice(mm) ▪ Long Axis- Longest diameter on an axial slice (mm) ▪ Average \ Max 3D \ Effective diameter (mm) ▪ Volume (mm3) Mean densities (HU)	Yes ▪ Volume (mm^3) ▪ Mean diameter (mm) ▪ Maximum diameter (mm) ▪ Short axis diameter (mm) ▪ Average/mini mum/maximum densities (HU)	No	Not relevant for this subject
Comparison and Matching	Yes	Yes	Yes	▪ EBW NM 2.0 (K111336) ▪ I4 (Integrated Intelligent Imaging Informatics) system • (K160315)
Comparison and matching automatic calculations between each follow-up scan and the previous scan	Yes ▪ Doubling time in days ▪ Percent (%) and absolute change of all numerical parameters (growth in nodule	Yes ▪ Elapsed time in days ▪ Doubling time in days Percent (%) growth in nodule volume	Yes	Not relevant for this subject

	long axis, short axis, average diameter, max 3D diameter, effective diameter, volume, mean HU).			
Workflow	▪ Detect and Segment ▪ Comparison and Matching ▪ Results	▪ Point-and-click detection ▪ Automated contouring ▪ Automated measurements ▪ Manual correction	▪ Detect and Segment ▪ Comparison and Matching ▪ Results	Not relevant for this subject
Loading multiple studies	Yes Up to 8 studies	Yes Up to 3 studies	Yes Up to 3 studies	Not relevant for this subject
Supporting Low-dose CT	Yes	Yes	No	Not relevant for this subject
Reporting results	Yes The results includes the following: • Patient related information • Dictation Table with Nodule result table and additional findings • Lung-RADS • Risk Calculator	Yes The results includes the following: • Dictation Table with Nodule result table • Lung-RADS • Fleischer Criteria	Yes The results includes the following: Dictation Table with Nodule result table	Not relevant for this subject
Printing Option	Yes	Yes	Yes	Not relevant for this subject

Philips Medical Systems Lung Nodule Assessment and Comparison Option (LNA application) and the identified predicate devices, primary- Toshiba's Lung Analysis Software (K151283) and predicate- Philips' Lung Nodule Assessment and Comparison option (K023785) are substantial equivalent in terms of indication for use and intended

users, design features, principle of operation and fundamental scientific technology, and safety and/or effectiveness.

The above listed technological differences are considered low risk, providing further support to clinicians in accessing current technologies or features. These functionalities are derived from reference predicate devices and were verified and validated, and do not raise new questions on safety and/or effectiveness.

These features have not changed the intended use and operational principles of the device. Therefore, the Lung Nodule Assessment and Comparison Option is substantially equivalent to the identified predicate devices , primary- Toshiba's Lung Analysis Software (K151283) and predicate- Philips' Lung Nodule Assessment and Comparison option (K023785)and the reference devices in terms of technological characteristics.

VII. Brief discussion of the nonclinical tests submitted, referenced or relied on

No performance standards for PACS systems or components have been issued under the authority of Section 514. Non-clinical performance testing has been performed on ISPP and demonstrates compliance with the following International and FDA-recognized consensus standards and FDA guidance document:

- ISO 14971 Medical devices – Application of risk management to medical devices
- IEC 62304 Medical device software – Software life cycle processes
- IEC 62366-1 Medical devices – Part 1:Application of usability engineering to medical devices
- Guidance for Industry and FDA Staff – Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices

Lung Nodule Assessment and Comparison Option was tested in accordance with Philips verification and validation processes. Verification and Validation tests have been performed to address intended use, the technological characteristics claims, requirement specifications and the risk management results.

For the Lung Nodule Assessment and Comparison Option (LNA), validation and verification

activities were conducted to provide objective evidence that the design meets user needs and intended use and application specification.

These validation activities assure that the lung and lobe segmentation, the comparison, as well as the nodule matching and propagation functionality, and the Prefill functionality for the Lung RADS score and the risk prediction are adequate from an overall product perspective.
The LNA application was validated using real recorded clinical data cases in order to simulate the actual use of the software .Each test case was evaluated for the complete clinical workflow.

In addition, a usability study was conducted according to the standards

The test results in this 510(k) premarket notification demonstrate that Lung Nodule Assessment and Comparison Option:

- Complies with the aforementioned international and FDA-recognized consensus standards and FDA guidance document, and
- Meets the acceptance criteria and is adequate for its intended use and specifications.

VIII. Brief discussion of clinical tests submitted, referenced or relied on

McWilliams, A et al[1] conducted a population-based prospective clinical study to determine factors predicting the probability that lung nodules detected on the first screening low-dose CT scans are malignant or will be found to be malignant on follow-up.

The authors indicated that the final parsimonious and full models showed excellent discrimination and calibration, with areas under the receiver-operating-characteristic curve of more than 0.90, even for nodules that were 10 mm or smaller in the validation set.

McWilliams A et al concluded that Predictive tools based on patient and nodule characteristics can be used to accurately estimate the probability that lung nodules detected on baseline screening low-dose CT scans are malignant.

The investigators analyzed data from two cohorts of participants undergoing low-dose CT screening. The development data set included participants in the Pan-Canadian Early Detection of

[1] McWilliams, A., Tammemagi, M.C., Mayo, J.R., Roberts, H., Liu, G., Soghrati, K., Yasufuku, K., Martel, S., Laberge, F., Gingras, M. and Atkar-Khattra, S.,. *Probability of cancer in pulmonary nodules detected on first screening CT.* New England Journal of Medicine, 2013; 369(10), 910-919.

Lung Cancer Study (PanCan). The validation data set included participants involved in chemoprevention trials at the British Columbia Cancer Agency (BCCA), sponsored by the U.S. National Cancer Institute. The final outcomes of all nodules of any size that were detected on baseline low-dose CT scans were tracked. Parsimonious and fuller multivariable logistic-regression models were prepared to estimate the probability of lung cancer.

IX. The conclusions drawn from the nonclinical and clinical tests

Verification and Validation (V&V) activities required to establish performance and functionality of Lung Nodule Assessment and Comparison Option were performed. Testing performed demonstrated the Lung Nodule Assessment and Comparison Option meets all defined functionality requirements and performance claims.

X. Overall conclusion:

The Lung Nodule Assessment and Comparison Option is substantially equivalent to the identified predicate devices , primary- Toshiba's Lung Analysis Software (K151283) and predicate- Philips' Lung Nodule Assessment and Comparison option (K023785), in terms of design features, fundamental scientific technology, indications for use, and safety and effectiveness. Additionally, verification and validation testing demonstrate the safety and efficacy of the device to meet its intended use and specification.

Philips Medical believes that the proposed device, Lung Nodule Assessment and Comparison Option, is substantially equivalence to its identified predicate device and is as safe and effective as its predicate device without raising any new safety and/or effectiveness concerns.