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
Indications for Use

510(k) Number (if known)
K163250

Device Name
Longitudinal Brain Imaging (LoBI) application

Indications for Use (Describe)
The Longitudinal Brain Imaging (LoBI) is a post-processing application to be used for viewing and evaluating neurological images provided by a magnetic resonance diagnostic device. The LoBI application is intended for viewing, manipulation, 3D-visualization and comparison of medical imaging and/or multiple time-points. The LoBI application enables visualization of information that would otherwise have to be visually compared disjointedly. The LoBI application provides analysis tools to help the user assess, and document changes in diagnostic and follow-up examinations. The LoBI application is designed to support the workflow by helping the user to confirm the absence or presence of lesions, including evaluation, quantification, follow-up and documentation of any such lesions.
The physician retains the ultimate responsibility for making the final diagnosis and treatment decision.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

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
PRASstaff@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.”
510(K) SUMMARY

510(k) Number K163250

Longitudinal Brain Imaging (LoBI) application

Date prepared: April 24, 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: Longitudinal Brain Imaging (LoBI) application
Device Classification Name System, Image processing, Radiological
Device Class Class II
Classification Panel LLZ
Product Code Radiological Image Processing Software
Regulation Description 21 CFR 892.2050

III. Device Description:

Longitudinal Brain Imaging (LoBI) application – 510k Submission
Philips Medical Systems’ Longitudinal Brain Imaging application (LoBI) is a post processing software application intended to assist in the evaluation of serial brain imaging based on MR data.

The LoBI application allows the user to view images, perform segmentation of lesions, along with segmentation editing tool and volumetric quantification of segmented volumes and quantitative comparison between time points. LoBI application provides automatic registration between studies from different time points, for longitudinal comparison.

The LoBI application provides a supportive tool for visualization of subtle differences in the brain of the same individual across time, which can be used by clinicians as the assessment of disease progression.

The physician retains the ultimate responsibility for making the final diagnosis based on image visualization as well as any segmentation and measurement results obtained from the application.

The LoBI application is intended to be used for adult population only

**Key Features**

LoBI application has the following key features:

1. Longitudinal comparison between brain images in multiple studies
2. Support for multi-slice MR sequences (2D and 3D) and allow user to use basic viewing operations such as: Scroll, pan, zoom, windowing and annotation
3. Identify pre-defined data types (pre-sets) and user created hanging layouts
4. Automatic registration between studies (same patient, different time-points)
5. Single mode: allows reviewing each of the launched studies, showing multiple sequences of the same study, using the whole reading space
6. Tissue segmentation and editing tools allowing volumetric measurement of different lesion types
7. Lesion management tool allowing matching between lesions in different studies to facilitate the assessment of differences over time
8. CoBI feature (Comparative Brain Imaging) - a supportive tool for visualization of subtle differences in lesions of the same individual across time for similar sequences. The CoBI feature provides a mathematical subtraction of scans yielding, after bias-field correction and intensity scaling, a color-coded image of the differences in intensity between two registered scans.
9. Results are displayed in tabular and graphical formats.
IV. Intended use:

The Longitudinal Brain Imaging (LoBI) is a post-processing application to be used for viewing and evaluating neurological images provided by a magnetic resonance diagnostic device. The LoBI application is intended for viewing, manipulation, 3D-visualization and comparison of medical imaging and/or multiple time-points. The LoBI application enables visualization of information that would otherwise have to be visually compared disjointedly. The LoBI application provides analysis tools to help the user assess, and document changes in diagnostic and follow-up examinations. The LoBI application is designed to support the workflow by helping the user to confirm the absence or presence of lesions, including evaluation, quantification, follow-up and documentation of any such lesions.

The physician retains the ultimate responsibility for making the final diagnosis and treatment decision.

V. Predicate Devices:

The Longitudinal Brain Imaging (LoBI) application is substantially equivalent to the following market-cleared devices:

Table 2-1 Predicates table

<table>
<thead>
<tr>
<th>Primary predicate</th>
<th>Device Name</th>
<th>Manufacturer</th>
<th>510k No</th>
<th>Date of Clearance</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>syngo.MR Neurology, syngo.MR Oncology</td>
<td>Siemens Medical Solution</td>
<td>K151353</td>
<td>August 07, 2015</td>
</tr>
<tr>
<td>Predicate</td>
<td>syngo TrueD</td>
<td>Siemens Medical Solution</td>
<td>K101749</td>
<td>August 16, 2010</td>
</tr>
</tbody>
</table>

Further to the predicate devices, Philips has identified the following currently marketed devices as reference predicate devices of proposed Longitudinal Brain Imaging (LoBI) application:
The proposed Philips Medical Systems Longitudinal Brain Imaging (LoBI) application and its predicate devices, syngo.MR Neurology, syngo.MR Oncology (K151353) and syngo TrueD (K101749), are substantially equivalent in regards to their intended uses, clinical indications, principle of operation and fundamental technology principles.

I4 (Integrated Intelligent Imaging Informatics) system (K160315), sTT under Spectral CT Applications (K150665), Lung Nodule Assessment and Comparison Option (K023785) and EBW NM2.0 (K111336) are reference devices for their additional technologies and support the additional application functionalities and enhanced capabilities.

### VI. Substantial Equivalence to Predicate Devices

<table>
<thead>
<tr>
<th>Feature</th>
<th>The proposed device: Longitudinal Brain Imaging (LoBI)</th>
<th>SIEMENS MEDICAL syngo.MR Neurology, syngo.MR Oncology (K151353)</th>
<th>SIEMENS MEDICAL syngo TrueD (K101749)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device Classification Name</td>
<td>System, Image processing, Radiological</td>
<td>Same</td>
<td>Same</td>
</tr>
<tr>
<td>Device Class</td>
<td>Class II</td>
<td>Class II</td>
<td>Class II</td>
</tr>
<tr>
<td>Classification Panel</td>
<td>Radiology</td>
<td>Radiology</td>
<td>Radiology</td>
</tr>
<tr>
<td>Feature</td>
<td>The proposed device: Longitudinal Brain Imaging (LoBI)</td>
<td>SIEMENS MEDICAL syngo.MR Neurology, syngo.MR Oncology (K151353)</td>
<td>SIEMENS MEDICAL syngo TrueD (K101749)</td>
</tr>
<tr>
<td>-------------------------</td>
<td>------------------------------------------------------------------------------------------------------------------------</td>
<td>-----------------------------------------------------------------</td>
<td>--------------------------------------</td>
</tr>
<tr>
<td>Product Code</td>
<td>LLZ</td>
<td>LLZ Subsequent LNH</td>
<td>LLZ</td>
</tr>
<tr>
<td>Regulation Description</td>
<td>Picture Archiving and communication system</td>
<td>Same</td>
<td>Same</td>
</tr>
<tr>
<td>Regulation Number</td>
<td>21 CFR 892.2050</td>
<td>21 CFR 892.2050</td>
<td>21 CFR 892.2050</td>
</tr>
<tr>
<td>Indication For Use</td>
<td>The Longitudinal Brain Imaging (LoBI) is a post-processing application to be used for viewing and evaluating neurological images provided by a magnetic resonance diagnostic device. The LoBI application is intended for viewing, manipulation, 3D-visualization and comparison of medical imaging and/or multiple time-points. The LoBI application enables visualization of information that would otherwise have to be visually compared disjointedly. The LoBI application provides analysis tools to help the user assess, and document changes in diagnostic and follow-up examinations. The LoBI application is designed to support the workflow by helping the user to confirm the absence or presence of lesions, including evaluation, quantification, follow-up and documentation of any such lesions. The physician retains the ultimate responsibility for making the final diagnosis and treatment decision.</td>
<td>The software comprising the syngo.MR post-processing applications are post-processing software / applications to be used for viewing and evaluating the designated images provided by a magnetic resonance diagnostic device. All of the software applications comprising the syngo.MR post-processing applications have their own indications for use. Syngo.MR Neurology is a syngo based post-processing software for viewing, manipulating, and evaluating MR neurological images. Syngo.MR Oncology is a syngo based post-processing software for viewing, manipulating, and evaluating MR oncological images. syngo TrueD is a medical diagnostic application for viewing, manipulation, 3D-visualization and comparison of medical images from multiple imaging modalities and/or multiple time-points. The application supports functional data, such as PET or SPECT as well as anatomical datasets, such as CT or MR. The images can be viewed in a number of output formats including MIP and volume rendering. syngo TrueD enables visualization of information that would otherwise have to be visually compared disjointedly. syngo TrueD provides analytical tools to help the user assess, and document changes in morphological or functional activity at diagnostic and therapy follow-up examinations. syngo TrueD is designed to support the oncological workflow by helping the user to confirm the absence or presence of lesions, including evaluation, quantification, follow-up and documentation of any such lesions.</td>
<td></td>
</tr>
</tbody>
</table>
### The proposed device:
Longitudinal Brain Imaging (LoBI)

<table>
<thead>
<tr>
<th>Feature</th>
<th>SIEMENS MEDICAL syngo.MR Neurology, syngo.MR Oncology (K151353)</th>
<th>SIEMENS MEDICAL syngo TrueD (K101749)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>lesions, including evaluation, quantification, follow-up and documentation of any such lesions. The application allows to store and export volume of interest (VOI) structures in DICOM RT format for use in radiation therapy planning systems. syngo TrueD allows visualization and analysis of respiratory gated studies to support accurate delineation of the target or treatment volume over a defined phase of the respiratory cycle and thus provide information for radiation therapy planning. Note: The clinician retains the ultimate responsibility for making the pertinent diagnosis based on their standard practices and visual comparison of the separate unregistered images. syngo TrueD is a complement to these standard procedures.</td>
<td></td>
</tr>
</tbody>
</table>

### Intended users
Radiologists and Technologists
Same
Same

### Type of imaging scans
MRI
MRI
CT, MR PET/CT and SPECT/CT

### Intended Body part
MR neurological images.
MR neurological images.
All body

### Loading multiple studies
Yes
Yes
Yes

### Support 2D anatomical sequences
Yes
Yes
Yes

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*Longitudinal Brain Imaging (LoBI) application – 510k Submission*
<table>
<thead>
<tr>
<th>Feature</th>
<th>The proposed device: Longitudinal Brain Imaging (LoBI)</th>
<th>SIEMENS MEDICAL syngo.MR Neurology, syngo.MR Oncology (K151353)</th>
<th>SIEMENS MEDICAL syngo TrueD (K101749)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Support 3D anatomical sequences</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Automatic image registration and synchronization</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Matching of lesions</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Semi-Automatic segmentation tools</td>
<td>Yes. Volumetric segmentation</td>
<td>Same</td>
<td>Same</td>
</tr>
<tr>
<td>Segmentation editing tools</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Matching between lesions</td>
<td>Yes. A suggestion for matching of segmented lesions between studies is provided to the user based on registration.</td>
<td>Yes. There is an option for matching of the segmented lesions</td>
<td>Yes. A suggestion for matching of segmented lesions between studies is provided to the user based on registration.</td>
</tr>
<tr>
<td>Automatic calculation of the measurements of segmented lesion</td>
<td>Yes. Including Volume, Min/Max/Mean etc.</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Follow-up (Tracking) option</td>
<td>Yes. Follow-up between studies. Includes a compare mode feature of visualization of subtle differences in the brain over time between two selected images</td>
<td>Yes. Follow-up between studies</td>
<td>Yes. Track changes in lesion’s parameters and follow-up between studies</td>
</tr>
<tr>
<td>Reporting</td>
<td>Results displayed in tabular and graphical formats.</td>
<td>Same</td>
<td>Same</td>
</tr>
<tr>
<td>DICOM Communication</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
</tbody>
</table>
The Philips Medical Systems Longitudinal Brain Imaging (LoBI) and the identified syngo.MR Neurology, syngo.MR Oncology (K151353) and syngo TrueD (K101749) are substantially equivalent in terms of indication for use and intended users, design features, principle of operation and fundamental scientific technology, and safety and/or effectiveness.

In conclusion, Philips believes that the proposed Longitudinal Brain Imaging (LoBI) does not introduce any new potential safety and/or effectiveness issues and is substantially equivalent to the identified predicate devices, syngo.MR Neurology, syngo.MR Oncology (K151353) and syngo TrueD (K101749).

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
- DICOM PS 3.1-3.18 standard Digital Imaging and Communications in Medicine (DICOM) Standard

Philips Medical Systems Longitudinal Brain Imaging (LoBI) application 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.

The following verification and validation testing were conducted with the Longitudinal Brain Imaging (LoBI) application:
**Verification** - the verification activities proves that the LoBI application includes the CoBI feature, function correctly and meets its specification. The verification testing includes the following testing:

➢ Full functionality test - a comprehensive list of test cases which covers a specific function/feature in the application. This test covers all of the detailed requirements according to the PRS (Product Requirement Specification).

➢ RMF testing - testing which covers the test that are specifically designed to check in the risk management file

**Validation** - the validation proves that the LoBI application meets the customer needs and its performance fulfills its intended functionality. The validation activities include real recorded clinical data cases in order to simulate the actual use of the application.

The test results in this 510(k) premarket notification demonstrate that *Longitudinal Brain Imaging (LoBI)*:

- 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**

The subject of this premarket submission, *Longitudinal Brain Imaging (LoBI)* application did not require clinical studies to support equivalence.

**IX. The conclusions drawn from the nonclinical and clinical tests**

Verification and Validation (V&V) activities required to establish performance and functionality of *Longitudinal Brain Imaging (LoBI)* were performed. Testing performed demonstrated the *Longitudinal Brain Imaging (LoBI)* meets all defined functionality requirements and performance claims.

**X. Overall conclusion:**
The *Longitudinal Brain Imaging (LoBI)* is substantially equivalent to the identified predicate devices, primary- syngo.MR Neurology, syngo.MR Oncology (K151353) and syngo TrueD (K101749) 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 specifications.

Philips Medical believes that the proposed device, *Longitudinal Brain Imaging (LoBI)* application, is substantially equivalent to its identified predicate device and is as safe and effective as its predicate device without raising any new safety and/or effectiveness concerns.