



Philips Medical Systems Technologies Ltd.
% Mr. Yoram Levy
QA/RA Consultant
Qsite
31 Haavoda Street
Binyamina 30500
ISRAEL

January 12, 2018

Re: K173588

Trade/Device Name: Illumeo System
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ, JAK
Dated: January 2, 2018
Received: January 8, 2018

Dear Mr. 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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<http://www.fda.gov/DICE>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

 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)

K173588

Device Name

Illumeo system

Indications for Use (Describe)

Illumeo system is an image management system intended to be used by trained professionals, including but not limited to radiologists.

Illumeo system is a software package used with general purpose computing hardware to acquire, store, distribute, process and display images and associated data throughout a clinical environment. The software performs digital image processing, measurement, manipulation and quantification of images, communication and storage.

This device is not to be used for mammography.

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.

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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: November 16, 2017
Submission Type Special 510(k): Device Modification submission

I. Submitter's name and address

Manufacturer: Philips Medical Systems Nederland B.V.
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Establishment Registration Number: 3003768277

Primary Contact Persons:

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II. Device information**Subject Device:**

Device Name: Illumeo system
Common/Usual Name: Imaging Informatics System
Classification:
 Classification name: Picture Archiving and Communications System
 Device class: Class II
 Classification regulation: 21 CFR 892.2050
 Classification panel: Radiology

Primary Product Code: LLZ
Secondary Product Code: JAK

Comment: Product commercial name was changed from I4 (Integrated Intelligent Imaging Informatics) System to Illumeo system for marketing reasons.

III. Predicate device information

Primary Predicate Device:

Trade name: I4 (Integrated Intelligent Imaging Informatics)
Manufacturer: Philips Healthcare Informatics, Inc.
510(k) clearance: K160315
Classification name: Picture Archiving and Communications System
Device class: Class II
Classification regulation: 21 CFR 892.2050
Classification panel: Radiology
Product code: LLZ, JAK

Reference Predicate Device:

Trade name: Intellispace Portal Platform
Manufacturer: Philips Medical Systems Nederland B.V.
510(k) clearance: K162025
Classification name: Picture Archiving and Communications System
Device class: Class II
Classification regulation: 21 CFR 892.2050
Classification panel: Radiology
Product code: LLZ

Trade name: Multi-Modality Tumor Tracking (MMTT) Application
Manufacturer: Philips Medical Systems Nederland B.V.
510(k) clearance: K162955
Classification name: Picture Archiving and Communications System
Device class: Class II
Classification regulation: 21 CFR 892.2050
Classification panel: Radiology
Product code: LLZ

IV. Device Description

Illumeo is an image management system intended to be used by trained professionals, including but not limited to radiologists.

Illumeo system is a software package used with general purpose computing hardware to acquire, store, distribute, process and display images and associated data throughout a clinical environment. The software performs digital image processing, measurement, manipulation and quantification of images, communication and storage.

This device is not to be used for mammography.

Illumeo is a medical software system offering a primary interpretation solution for visualization and evaluation a variety of medical images deriving from various imaging modalities as well as non-imaging information. Illumeo interconnects with clinical imaging and non-imaging data sources to present in addition to images non-imaging data in patient context.

Comment: Product commercial name was changed from I4 (Integrated Intelligent Imaging Informatics) System to Illumeo for marketing reasons.

Device modifications

The proposed Illumeo system includes the following minor modifications, compared to the primary predicate device, I4 (Integrated Intelligent Imaging Informatics) system (K160315).

Description of the device modifications:

1. Improved performance of the software image management system –communication to PACS using dedicated interfaces and automatic preprocessing on data arrival for enhanced performance.
2. Integration with IntelliSpace PACS – improvements in data retrieval through FHIR interface and reporting workflow, interface with Electronic Medical Record (EMR) and Radiology Information System (RIS)
3. Scalability – Illumeo v2.0 supports up to 50 concurrent users using hosted client and up to 150 concurrent users using enterprise viewer.
4. Multimodality and Multivendor support:
Additional Multimodality supported - SPECT, improved Multivendor support, support for Presentation states (PR), PET/CT fusion of a single study
5. Patient briefing - including additional information such as prior findings, recent Lab Results, Scanned documents, Patient Location and type.
6. 2D and 3D viewing – enhanced additional tools
7. Findings creation and management - improvements including Match finding feature enabling track and measure change over time.

8. Comparison and Synchronization – enhanced capabilities such as compare mode between current and prior studies, comparison inspector presenting the same region of interest in the same study or compared to prior studies, manual link/unlink datasets.
9. Hanging protocols (HP) – functionality which enables to present presets that define how a study is displayed (layout), which series will be displayed by default and what viewing parameters are used. Hanging Protocols are multi - modality as per study type.
10. Vascular Inspection mode/ Vascular Quantification inspector – enhanced vascular inspection mode including local vascular inspection mode
11. User Interface Improvements
12. Enterprise Viewer – Illumeo system includes Enterprise viewer - a fully HTML5 based viewer version, embedding Findings Presenter functionalities to address Enterprise clinical review by the specialists. Enterprise viewer zero footprint viewer requires no installation, and runs on most common operating systems and browsers. Enterprise Viewer is not intended to be used on mobile platforms.

The proposed Illumeo system includes modifications which are considered minor technology changes mainly designated to provide users further support in visualization.

The presented device modifications do not affect/change neither Intended Use nor alter the fundamental scientific technology of the device.

Therefore Philips believes a Special 510(k) is the appropriate type of submission

V. Indications for Use

Illumeo system is an image management system intended to be used by trained professionals, including but not limited to radiologists.

Illumeo system is a software package used with general purpose computing hardware to acquire, store, distribute, process and display images and associated data throughout a clinical environment. The software performs digital image processing, measurement, manipulation and quantification of images, communication and storage.

This device is not to be used for mammography.

Indications for Use Discussion

The proposed device, Illumeo system, is a software package used with general purpose computing hardware to acquire, store, distribute, process and display images and associated data throughout a clinical environment, identical to the primary predicate device, I4 (Integrated Intelligent Imaging Informatics) system (K160315).

Illumeo system software is designed to perform digital image processing, measurement, manipulation and quantification of images, communication and storage with indications for use identical to the primary predicate device, I4 (Integrated Intelligent Imaging Informatics) system (K160315).

The Indications for Use statement for I4 (Integrated Intelligent Imaging Informatics) is **identical** compared to the primary predicate device, I4 (Integrated Intelligent Imaging Informatics) system (K160315).

Based on the above, the proposed Illumeo system is considered substantially equivalent to the currently marketed and primary predicate device I4 (Integrated Intelligent Imaging Informatics) system (K160315), in terms of Indications for use.

VI. Comparison of Technological Characteristics with the Predicate Device

The proposed Illumeo system is an evolution of previously cleared I4 (Integrated Intelligent Imaging Informatics) system (K160315), with additional minor modifications deriving from the identified predicate and reference devices.

Illumeo v2.0 is an evolution of Illumeo v1.0 system, formerly also known as I4 (Integrated Intelligent Imaging Informatics) System. The product commercial name was changed from I4 (Integrated Intelligent Imaging Informatics) System to Illumeo system, for marketing reasons.

Illumeo system is a software package used with general purpose computing hardware. Illumeo system uses the standard principles of operation typically seen in PACS systems such as database and image management systems, image processing tools, and standard measurement tools. Both the proposed device and the primary predicate device, I4 (Integrated Intelligent Imaging Informatics) system (K160315), provide Diagnostic Review Solution for radiology, utilizing client –server technology, storage capabilities, communication and interoperability with hospital systems.

Both the proposed device and the primary predicate device, I4 (Integrated Intelligent Imaging Informatics) system (K160315), offer a primary interpretation solution for visualization and evaluation variety of medical images deriving from various imaging modalities as well as non-imaging information. Illumeo and its primary predicate device interconnect with clinical imaging and non-imaging data sources to present in addition to images non-imaging data in patient context.

The proposed device, Illumeo system, has implemented features designated to bring the product up to date with current technologies and customer requests.

A comparison table below (please see Table No.2- 1 below) provides a comparison which outlines a high-level overview of the differences and similarities between Illumeo system and the primary predicate device, I4 (Integrated Intelligent Imaging Informatics) system (K160315).

Table No.2- 1 Technological characteristics comparison

#	Specification / Feature	Illumeo System (Proposed device)	I4 (Integrated Intelligent Imaging Informatics) System (K160315) (Primary Predicate Device)
1.	Software Image management system	Yes	Yes
2.	Hardware Platform requirements	Yes	Yes
System Configuration			
3.	Windows Operating System	Yes	Yes
4.	TCP-IP Network Protocol	Yes	Yes
5.	Supports High Resolution Diagnostic Monitors	Yes	Yes
6.	Storage capabilities	Yes	Yes
7.	Multiple monitor support	Yes	Yes
Communication and Interoperability with other image management systems			
8.	Supports DICOM studies received from different modalities types	Yes CT, MR, US, XA, DX, CR, RF, PET, SC, SPECT, as well as hospital/radiology information system	Yes
9.	Mammography	No	No
10.	Accepts patient and exam updates	Yes	Yes
Operating Platform requirements			
11.	Client-server technology	Yes	Yes

#	Specification / Feature	Illumeo System (Proposed device)	I4 (Integrated Intelligent Imaging Informatics) System (K160315) (Primary Predicate Device)
12.	Thin client installer	Yes	Yes
13.	Multiple concurrent user support	Yes <ul style="list-style-type: none"> ▪ Up to 50 concurrent users using hosted client ▪ Up to 150 concurrent users using Enterprise Viewer 	Yes <ul style="list-style-type: none"> ▪ Up to 10 concurrent users
Management tools			
14.	Auditing Tool	Yes	Yes
15.	Client installer	Yes	Yes
16.	System management	Yes	Yes
17.	Security and Privacy	Yes	Yes
Viewing and Image Processing			
18.	Supported Data and Multi Modalities	Supports receiving, sending, storing and displaying studies received from the following modalities via DICOM: CT, MR, US, XA, DX, CR, RF, PET, SPECT and SC as well as hospital /radiology information systems.	Supports receiving, sending, storing and displaying studies received from the following modalities via DICOM: CT, MR, US, XA, DX, CR, RF, PET and SC as well as hospital /radiology information systems.
19.	2D viewing capabilities	Yes	Yes

#	Specification / Feature	Illumeo System (Proposed device)	I4 (Integrated Intelligent Imaging Informatics) System (K160315) (Primary Predicate Device)
20.	3D viewing capabilities	Yes	Yes
21.	Finding creation and management tool	Yes	Yes
22.	Comparison and Synchronization between volumetric series	Yes	Yes
23.	Hanging protocols (HP)	Yes	Yes
24.	Advanced vessel analysis visualization and evaluation mode - Vascular Quantification Inspector (Vascular Inspection Mode)	Yes	Yes
25.	Incorporation of non-imaging data in patient context (Patient Briefing)	Yes	Yes
26.	Enterprise Diagnostic web viewer	Yes	Yes
27.	Non - Diagnostic Enterprise web viewer	Yes	Yes

The proposed device, Illumeo system, has implemented features designated to bring the product up to date with current technologies and customer requests.

Presented technological differences are considered low risk, providing further support to users/clinicians in visualization. All the above listed device modifications were verified and validated demonstrating that the design outputs of the modified device meet the design input requirements and do not raise new questions on safety and/or effectiveness.

These features have not changed the intended use and the fundamental scientific technology of the device.

Therefore, the proposed Illumeo system is substantially equivalent to the currently marketed primary predicate device I4 (Integrated Intelligent Imaging Informatics) System (K160315) in terms of technological characteristics.

Conclusion

The proposed Illumeo system is **Substantially Equivalent** to the currently marketed primary predicate device, I4 (Integrated Intelligent Imaging Informatics) System (K160315), in terms of Indication for Use, design features, fundamental scientific technology, and safety and/or effectiveness

VII. Performance Data

Section 16 ‘Software’ provides a summary of the technical documentation which includes non-clinical verification and validation tests. These tests are performed with regards to the intended use, the technical claims, the requirement specifications and the risk management results, and according to the following International and FDA-recognized consensus standards and FDA guidance document.

The following performance data were provided in support of the substantial equivalence determination.

Summary of Non-clinical testing

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 Illumeo system 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
- NEMA-PS 3.1- PS 3.20 Digital Imaging and Communications in Medicine (DICOM)
- Guidance for Industry and FDA Staff – Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices

Illumeo system 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 test results in this Special 510(k): Device Modification submission demonstrates that Illumeo system:

- 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 user needs.

Additionally, the risk management activities show that all risks are sufficiently mitigated, that no new risks are introduced, and that the overall residual risks are acceptable. Therefore, Illumeo system is substantially equivalent to the currently marketed primary predicate device I4 (Integrated Intelligent Imaging Informatics) System (K160315) in terms of safety and effectiveness.

Summary of Clinical Testing

The subject of this Special 510(k): Device Modification submission, Illumeo system did not requires clinical studies to support equivalence.

VIII. Substantial Equivalence Conclusion

The Illumeo system is substantially equivalent to the currently marketed primary predicate device (Integrated Intelligent Imaging Informatics) System (K160315) in terms of Indications for Use, design features, fundamental scientific technology, and safety and/or effectiveness. Additionally, substantial equivalence was demonstrated with non-clinical performance testing. Verification and Validation (V&V) activities were performed for proposed Illumeo system and demonstrated that the predetermined acceptance criteria were successfully met. The non-clinical performance tests provided in this Special 510(k): Device Modification submission demonstrated that the proposed Illumeo system is as safe and effective as its primary predicate device I4 (Integrated Intelligent Imaging Informatics) System (K160315) without raising any new safety and/or effectiveness concerns.