January 14, 2022

Philips Medical Systems Nederland, B.V.
℅ Michael Chilbert
Regulatory Affairs Engineer
Veenpluis 4-6
Best Noord-Brabant, 5684 PC
NETHERLANDS

Re: K210760
Trade/Device Name: Precise Image
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed Tomography X-Ray System
Regulatory Class: Class II
Product Code: JAK
Dated: December 10, 2021
Received: December 13, 2021

Dear Mr. Michael Chilbert:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Laurel Burk, Ph.D.
Assistant Director
Diagnostic X-ray Systems Team
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K210760

Device Name
Precise Image

Indications for Use *(Describe)*
The Precise Image is a reconstruction software application for a Computed Tomography X-Ray System intended to produce images of the head and body by computer reconstruction of x-ray transmission data taken at different angles and planes. These devices may include signal analysis and display equipment, patient and equipment supports, components and accessories. Precise Image has been evaluated and available on preselected reference protocols for adult subjects. Precise Image is not indicated for use in pediatric subjects.

The CT system with Precise Image is indicated for head, whole body and vascular X-ray Computed Tomography applications. These scanners are intended to be used for diagnostic imaging.

Precise Image uses an Artificial Intelligence powered reconstruction algorithm that is designed for low radiation dose, provides lower noise, and improves low contrast detectability.

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.

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SECTION 5 510(K) SUMMARY

510(k) Summary for K210760

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

Date Prepared:	January 13, 2022	
Manufacturer:	Philips Medical Systems Nederland B.V. Veenpluis 6, 5684 PC BEST The Netherlands Establishment Registration Number: 3015777306	
Primary Contact Person:	Michael Chilbert, Ph.D., P.E. Regulatory Affairs Engineer Phone: 440-869-4576 E-mail: Michael.chilbert@philips.com	
Secondary Contact Person:	Douglas Kentz Director of Regulatory Affairs Phone: (262) 389-7369 E-mail: douglas.kentz@philips.com	
Device*:*	Trade Name:	Precise Image
	Common name:	Computed Tomography x-Ray System
	Classification Name:	Computed Tomography x-Ray System
	Classification Regulation:	21CFR 892.1750
	Classification Panel:	Radiology
	Device Class:	II
	Primary Product Code:	JAK
	Secondary Product Code:	Not Applicable
Predicate Device:	Trade Name:	Incisive CT
	Manufacturer:	Philips Healthcare (Suzhou) Co., Ltd.
	510(k) Clearance:	K180015
	Classification Name:	Computed Tomography X-Ray System
	Classification Regulation:	21CFR §892.1750
	Classification Panel:	Radiology
	Device Class:	Class II
	Product Code:	JAK
Reference Device:	Trade Name:	Brilliance iCT
	Manufacturer:	Philips Medical Systems Nederland B.V.
	510(k) Clearance:	K162838
	Classification Name:	Computed Tomography X-Ray System
	Classification Regulation:	21CFR §892.1750
	Classification Panel:	Radiology
	Device Class:	Class II
	Product Code:	JAK

Device Description:

The proposed Precise Image is a reconstruction software application that may be used on a Philips whole-body computed tomography (CT) X-Ray System. Precise Image is a robust reconstruction software application, utilizing technological advancements in Artificial Intelligence and a Convolutional Neural Networks (CNN), When used, Precise Image generates CT images that provides an image appearance similar to traditional FBP images while reducing dose and improving image quality.

The implemented algorithm includes 5 user-adjustable settings to match the Radiologist's preference for dose reduction and image quality.

The proposed Precise Image reconstruction has been trained on and may be used on the currently marketed predicate device Philips Incisive CT System (K180015).

Indications for Use / Intended Use:

The Precise Image is a reconstruction software application for a Computed Tomography X-Ray System intended to produce images of the head and body by computer reconstruction of x-ray transmission data taken at different angles and planes. These devices may include signal analysis and display equipment, patient and equipment supports, components and accessories. Precise Image has been evaluated and available on preselected reference protocols for adult subjects. Precise Image is not indicated for use in pediatric subjects.

The CT system with Precise Image is indicated for head, whole body and vascular X-ray Computed Tomography applications. These scanners are intended to be used for diagnostic imaging.

Precise Image uses an Artificial Intelligence powered reconstruction algorithm that is designed for low radiation dose, provides low noise, and improves low contrast detectability.

Technological Characteristics

The proposed Precise Image reconstruction software application, has the same fundamental design characteristics and are based on comparable technologies found in the currently marketed predicate device Philips Incisive CT (K180015)

This 510(k) submission addresses the following:

- Precise Image is an Artificial Intelligence powered reconstruction algorithm that is designed for low radiation dose, provides low noise, and improves low contrast detectability as compared to iDose, as well as improve image appearance that more closely resembles Filtered Back Projection (FBP) at higher doses.
- The currently marketed predicate Philips Incisive CT (K180015) is being used for diagnostic imaging in radiology, interventional radiology and cardiology and in oncology as part of treatment preparation and radiation therapy planning. The fundamental scientific technology and design of the proposed Precise Image reconstruction software application is equivalent to the currently marketed predicate device Philips Incisive CT (K180015).

Technological Characteristics Comparison Design and Fundamental Scientific Technology			
Device	**Predicate Device: Incisive CT System (K180015)**	**Proposed Device: Precise Image software application**	**Conclusion**
Application	Head, Body, Vascular and Cardiac	Head, Body and Vascular	Proposed device has scan types found in the predicate,
Scan Regime	Continuous Rotation	Continuous Rotation	Scan data used for reconstruction - Identical,
Scan Field of View	Up to 500 mm	Up to 500 mm	Identical
Scan modes	Surview Axial-after-Axial Dynamic Scan Helical Scan	Axial-after-Axial Helical Scan	Proposed device has scan types found in the predicate
Low Contrast Resolution (20 cm Catphan phantom)	4 mm @ 0.3% @ 22 mGy CTDIvol	5 mm @ 0.3% @ 5.5 mGy CTDIvol	Improved, better low contrast resolution at lower dose levels.
Minimum Scan Time	0.35 sec for 360° rotation	0.35 sec for 360° rotation	Identical
Noise in Standard Mode (as measured on 21.6 cm water-equivalent)	0.27% at 27 mGY	0.27% at 27 mGY	Identical
Noise Reduction and Low Contrast Detectability	N/A – Standard mode (baseline for claim)	achieving up to 85% lower noise at 80% lower dose and 60% better low contrast detectability	Improved, better noise reduction and low contrast detectability
Noise Power Spectrum	N/A – Standard mode (baseline for claim)	Where noise is reduced by at least 50%, the system shall shift the noise power spectrum of images by no more than 6% as compared to the same data reconstructed without Precise Image	Will not shift NPS more than 6%
Application	Head, Body, Vascular and Cardiac	Head, Body and Vascular	Proposed device has scan types found in the predicate.
Scan Regime	Continuous Rotation	Continuous Rotation	Scan data used for reconstruction - Identical.

Based on the information provided above, the proposed Precise Image reconstruction software application for Philips CT Systems is considered substantially equivalent to the currently marketed predicate device Philips Incisive CT (K180015), in terms of fundamental scientific technology.

Summary of Non-Clinical Performance Data:

Non-clinical performance testing has been performed on the proposed Precise Image reconstruction software application for CT Systems.

Philips CT Systems, comply with the following International and FDA recognized consensus standards and FDA guidance document(s).

- IEC 60601-1:2005 (Third Edition) + CORR. 1:2006 + CORR. 2:2007 + A1:2012 (or IEC 60601-1: 2012 reprint) (FDA Recognition Number: 19-4)
- IEC 60601-1-2:2014: (FDA Recognition Number :19-8)
- IEC 60601-1-3:2008+A1:2013 (FDA Recognition Number: 12-269)
- IEC 60601-1-6:2010 +A1: 2013 (FDA Recognition Number: 5-89)
- IEC 60601-2-44:2009/AMD2:2016 (FDA Recognition Number: 12-302)
- IEC 62304:2006 + A1: 2015 (FDA Recognition Number: 13-79)
- ISO 10993-1:2009/Cor.1:2010 (FDA Recognition Number: 2-220)
- ISO 14971 2nd Edition. (FDA Recognition Number: 5-40)

Device Specific Guidance Document:

- Guidance for Industry and FDA Staff – Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" (issued May 11, 2005)
- International and FDA-recognized consensus IEC 62304 "Medical device software – Software life cycle processes" (Edition 1.1, 2006). FDA/CDRH recognition number 13-79.
- Proposed Regulatory Framework for Modifications to Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD) Discussion Paper. (April 2, 2019)

Design Verification planning and testing was conducted at the sub-system and at the system level. The sub-systems are tested against the sub-system requirements specifications (SSRS) and the system level verification is conducted against the system requirement specifications (SRS). System and sub-system verification activities demonstrate the system or sub-systems meet the established system and sub-system level design input requirements. System and sub-system level requirements may be verified by manual test, automated test, inspection/analysis, or any combination of the three. Design verification also includes Image Quality verification and risk analysis/risk mitigation testing.

The traceability between the requirements, the hazard mitigations and the test protocols are described in the Traceability Matrix. The Traceability Matrix also shows the overall test results per requirement and per hazard mitigation. The summary and conclusion of results are provided in the System Verification Test Report.

Non-Clinical design validation testing covered the intended use and commercial claims Validation testing included clinical image evaluation and workflow validation.

All these tests were used to support substantial equivalence of the proposed Precise Image reconstruction software application and demonstrate that the proposed Precise Image reconstruction software application for CT Systems:

- Maintains compliance with the aforementioned international and FDA-recognized consensus standards and/or FDA device specific guidance document, and;
- Meets the acceptance criteria and is adequate for its intended use.

Therefore, the proposed Precise Image reconstruction software application for Philips CT Systems is considered substantially equivalent to the currently marketed predicate device Philips Incisive CT (K180015) in terms of safety and effectiveness.

Summary of Clinical Performance Data:

The proposed Precise Image reconstruction software application for CT Systems did not require any external clinical study. A comparative image evaluation study was performed on 55 image set pairs from Precise Image and the predicate Incisive CT and Brilliance iCT by 6 board certified radiologists to evaluate Diagnostic Confidence, Sharpness, Noise level, Image texture and Artifacts on a five point Likert scale. The substantial equivalence to the currently marketed predicate device Philips Incisive CT (K180015) was demonstrated with the following attributes:

- Indication for use;
- Technological characteristics;
- Non-clinical and clinical performance testing; and
- Safety and effectiveness.

Sample clinical images are provided with this submission, which were reviewed and evaluated by certified radiologists. All images were evaluated to have good image quality.

Substantial Equivalence Conclusion:

The proposed Precise Image reconstruction software application for Philips CT Systems is substantially equivalent to the currently marketed predicate device Philips Incisive CT (K180015) in terms of design, features and fundamental scientific technology. The Precise Image reconstruction software application for Philips CT Systems does not introduce any new risk nor impact safety and effectiveness.

Additionally, substantial equivalence was demonstrated by non-clinical and clinical (verification and validation) performance tests provided in this 510(k) premarket notification. These tests demonstrate that the proposed Precise Image reconstruction software application for CT Systems complies with the requirements specified by Philips Medical Systems Nederland B.V. and the international and FDA-recognized consensus standards and is as safe and effective as its currently marketed predicate device Philips Incisive CT (K180015) without raising any new safety and/or effectiveness concerns.