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

August 17, 2021

Re: K201573
Trade/Device Name: Brain Perfusion (BP) application
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed Tomography X-Ray System
Regulatory Class: Class II
Product Code: JAK, LLZ
Dated: July 9, 2021
Received: July 13, 2021

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. 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,

For

Thalia T. Mills, Ph.D.
Director
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)*
K201573

Device Name
Brain Perfusion (BP) application

Indications for Use *(Describe)*
The Philips Medical Systems' Brain Perfusion (BP) application is a post processing software application intended to assist with the evaluation of an area of interest, to generate qualitative and quantitative information about changes in image intensity over time. It supports the analysis of dynamic/serial CT after injection of contrast agent, by calculating the parameters related to brain perfusion and displays the results as a composite (single image that is calculated from a set of time course images at a single location) images.

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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K201573

510(K) SUMMARY

Brain Perfusion (BP) application

Date prepared: July 4, 2021

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	Ms. Vered Nitzan Regulatory Affairs Lead, ICAP Philips Medical Systems Nederland B.V Phone: (972)54-9797047 E-mail: vered.nitzan@philips.com

II. Device information

Trade name:	***Brain Perfusion (BP) application***
Device Classification Name	Computed tomography x-ray system
Device Class	Class II
Classification Panel	JAK, LLZ
Product Code	Radiological Image Processing Software
Regulation Description	21 CFR 892.1750

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III. Device Description:

The Philips Medical Systems' Brain Perfusion (BP) application is a post processing software to be used as an advanced visualization application of CT brain perfusion images.

The BP application is used to support the analysis of dynamic and/or serial CT brain images after injection of contrast. The BP application is intended to assist with the evaluation of an area of interest, and to generate qualitative and quantitative information about changes in image intensity over time.

The BP application presents the results as a composite (single image that is calculated from a set of time course images at a single location) images and provides perfusion parameters maps. The following parameters relate to brain perfusion are calculated: Cerebral Blood Flow (CBF), Cerebral Blood Volume (CBV), local bolus timing (Time to Peak (TTP)/Time to Maximum (Tmax)) and Mean Transit Time (MTT) and supports processing and visualization of Permeability maps.

The physician retains the ultimate responsibility for making the final diagnosis.

Key Features:

The Brain Perfusion (BP) application has the following key features:

1. Support visualization and processing of dynamic and /or serial brain CT scans with contrast agent injection.
2. Display the results as composite (single image calculated from a dynamic set of images at a single location) images (tMIP images).
3. Display time-density curves reflecting the HU contrast enhancement tracked for an ROI over time.
4. Supports detection of reference artery, reference vein, mirror line placement and brain mask.
5. Supported option for 3D motion correction with anatomical alignment.
6. Provides Perfusion maps of Cerebral Blood Volume (CBV), Mean Transit Time (MTT), Cerebral Blood Flow (CBF) and Time to Peak (TTP), using the time arrival sensitive method.

7. Provide Perfusion maps of Time to maximum (Tmax), using the time arrival insensitive method.
8. Provides summary maps according to default thresholds. The user may manually adjust the summary maps thresholds and/or different parameters according to the physician's preference.
9. Provides colored warning strips (Traffic Lights), indicating the quality of the Brain Perfusion data (acquisition).
10. Supports processing and visualization of permeability maps
11. Display pre-defined ROI templates for localized quantitative evaluation of perfusion information.
12. Supports automatic workflow – Brain Perfusion application can generate and sends automatic results to defined external destination.

IV. Intended use and Indications for use:

The Philips Medical Systems' Brain Perfusion (BP) application is a post processing software application intended to assist with the evaluation of an area of interest, to generate qualitative and quantitative information about changes in image intensity over time. It supports the analysis of dynamic/serial CT after injection of contrast agent, by calculating the parameters related to brain perfusion and displays the results as a composite (single image that is calculated from a set of time course images at a single location) images.

V. Predicate Devices:

The following table shows the predicate and reference devices of the proposed Philips Medical Systems Brain Perfusion (BP) application:

	Device Name	Manufacturer	510k No	Date of Clearance
Primary predicate	Brain Perfusion Application	Philips Medical Systems	K182716	May 29, 2019
Reference device	CARESTREAM Vue PACS	CARESTREAM HEALTH, INC.	K153103	February 12, 2016

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The proposed Philips Medical Systems Brain Perfusion (BP) application and its predicate device, Brain Perfusion Application (K182716), are substantially equivalent in regards to their intended uses, clinical indications, principle of operation and fundamental technology principles.

In addition to the predicate device, Philips identified the following currently marketed device, as a reference device of the proposed Brain Perfusion Application: CARESTREAM Vue PACS (K153103). The latter utilizes the added functionality which is the subject of this submission.

VI. Substantial Equivalence to Predicate Devices

Feature	The proposed device: Brain Perfusion (BP) Application	Primary Predicate: Philips Brain Perfusion Application (K182716)	Reference Predicate: CARESTREAM Vue PACS (K153103)
Device Classification Name	System, Image processing, Radiological	System, Image processing, Radiological	System, Image processing, Radiological
Device Class	Class II	Class II	Class II
Classification Panel	Radiology	Radiology	Radiology
Product Code	JAK, LLZ	JAK, LLZ	LLZ
Regulation Description	Computed tomography x-ray system	Computed tomography x-ray system	Picture Archiving and communication system
Regulation Number	21 CFR 892.1750	21 CFR 892.1750	21 CFR 892.2050
Indication for Use	The Philips Medical Systems' Brain Perfusion (BP) application is **a post processing software application intended to assist with the**	The Philips Medical Systems' Brain Perfusion (BP) application is a **post processing software application intended to assist with the**	The CARESTREAM Vue PACS is an **image management system**… …The system contains a **Perfusion module** with

Feature	The proposed device: Brain Perfusion (BP) Application	Primary Predicate: Philips Brain Perfusion Application (K182716)	Reference Predicate: CARESTREAM Vue PACS (K153103)
	evaluation of an area of interest, to generate qualitative and quantitative information about changes in image intensity over time. It supports the analysis of dynamic/serial CT after injection of contrast, by calculating the parameters related to brain perfusion and displays the results as a composite (single image that is calculated from a set of time course images at a single location) images.	**evaluation of an area of interest, to generate qualitative and quantitative information about changes in image intensity over time. It supports the analysis of dynamic/serial CT after injection of contrast, by calculating the parameters related to brain perfusion and displays the results as a composite (single image that is calculated from a set of time course images at a single location) images.**	interactive tools to ease the process of **analyzing and comparing Computed Tomography Perfusion (CTP)** images of adult patients.
Intended users	Trained professionals including but not limited to physicians and medical technicians.	Trained professionals including but not limited to physicians and medical technicians.	Trained professionals including but not limited to physicians and medical technicians.
Intended Body part	Brain	Brain	Brain

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Feature	The proposed device: Brain Perfusion (BP) Application	Primary Predicate: Philips Brain Perfusion Application (K182716)	Reference Predicate: CARESTREAM Vue PACS (K153103)
Type of scans	**CT perfusion scans**	**CT perfusion scans**	… **CT Perfusion (CTP)**…
Automatic motion correction	Yes	Yes	Yes
CBV parametric map	Yes	Yes	Yes
CBF parametric map	Yes	Yes	Yes
MTT parametric map	Yes	Yes	Yes
Tmax parametric map	Yes	No	Yes
Methods used for providing perfusion maps	**Time arrival sensitive method and time arrival insensitive method**	**Time arrival sensitive method**	**Time arrival sensitive method and insensitive method**
Time to Peak Enhancement (TTP)	Yes	Yes	Yes
Visualization of permeability imaging map	Yes	Yes	Yes
Support detection of reference artery	Yes	Yes	Yes
Support detection of reference vein	Yes	Yes	Yes
Volume calculation: marking the total volume of affected tissue	Yes	Yes	Yes

Feature	The proposed device: Brain Perfusion (BP) Application	Primary Predicate: Philips Brain Perfusion Application (K182716)	Reference Predicate: CARESTREAM Vue PACS (K153103)
Region of Interest	Yes The user can select and draw the Region of Interest	Yes The user can select and draw the Region of Interest	Yes Display results in tabular and graphical format
Result	Display results in tabular and graphical format	Display results in tabular and graphical format	Display results in tabular and graphical format
Export image Option	Yes	Yes	Yes
DICOM format communication	Yes	Yes	Yes
Support automatic workflow	Yes	Yes	Yes

The proposed Philips Medical Systems ***Brain Perfusion (BP)*** application and its predicate devices, the primary Brain Perfusion (BP) application (K182716) is substantially equivalent in regards to their intended uses, clinical indications, principle of operation and fundamental technology principles.

In conclusion, Philips believes that the ***Brain Perfusion (BP) application*** does not introduce any new potential safety and/or effectiveness issues and is substantially equivalent to the identified predicate device, Brain Perfusion (BP) application (K182716).

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

Non-clinical performance testing has been performed on ***Brain Perfusion (BP) application*** 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
- NEMA PS 3.1-3.20 - Digital Imaging and Communications in Medicine (DICOM) Standard
- IEC 62366-1 Medical devices - Part 1: Application of usability engineering to medical devices

Philips Medical Systems ***Brain Perfusion (BP) 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 test results in this 510(k) premarket notification demonstrates that ***Brain Perfusion (BP) application:***

- 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.

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

The subject of this premarket submission, ***Brain Perfusion (BP) 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 ***Brain Perfusion (BP) application*** were performed. Testing performed demonstrated the ***Brain Perfusion (BP) application*** meets all defined functionality requirements and performance claims.

X. Overall conclusion:

The ***Brain Perfusion (BP) application*** is substantially equivalent to the identified predicate device, Brain Perfusion (BP) application (K182716) 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**,** ***Brain Perfusion (BP) 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.