January 24, 2020

Philips Medical Systems MR Finland
℅ Janne Marvola, Ph.D.
Regulatory Engineer
Ayritie 4
01510 Vantaa
FINLAND

Re: K193109
Trade/Device Name: MRCAT brain
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: Class II
Product Code: MUJ
Dated: November 4, 2019
Received: November 8, 2019

Dear Dr. Marvola:

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,

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)*
K193109

Device Name
MRCAT Brain

Indications for Use *(Describe)*

MRCAT Brain is a software add-on for Ingenia, Ingenia Ambition, and Ingenia Elition MR systems.

Intended Use:
MRCAT imaging is intended to provide the operator with information of tissue properties for radiation attenuation estimation purposes in photon external beam radiotherapy treatment planning.

Indications for use:
MRCAT Brain is indicated for radiotherapy treatment planning for primary and metastatic brain tumor patients.

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."

6. 510(k) Summary

510(k) Summary of Safety and Effectiveness

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

Date Prepared:	January 20, 2020	
Manufacturer:	Philips Medical Systems MR Finland Äyritie 4 01510 Vantaa, Finland Establishment Registration Number: 9680194	
Primary Contact Person:	Janne Marvola Regulatory Engineer Phone: +358-40-126 1214 Fax: +358-9-3487 2406 E-mail: regulatory.mr.therapy@philips.com	
Secondary Contact Person	Osku Ilvonen Head of Q&R Phone: +358-40-552 6197 Fax: +358-9-3487 2406 E-mail: osku.ilvonen@philips.com	
Device Name:	**MRCAT brain**	
Classification:	Classification Name:	Medical charged-particle radiation therapy system
	Classification Regulation:	21 CFR §892.5050
	Classification Panel:	Radiology
	Device Class:	Class II
	Product code:	MUJ (System, Planning, Radiation Therapy Treatment)

Predicate Device:	Trade Name:	MRCAT Pelvis
	Manufacturer:	Philips Medical Systems MR Finland
	510(k) Clearance:	K182888 (April 30, 2019)
	Classification Regulation:	21 CFR, Part 892.5050
	Classification Name:	Radiation Therapy Planning System
	Classification Panel:	Radiology
	Device Class:	Class II
	Product Code:	MUJ (System, planning, radiation therapy treatment)
Reference Device:	Trade Name:	AcQPlan 5.0
	Manufacturer:	Philips Medical Systems MR Finland
	510(k) Clearance:	K013644 (September 12, 2002)
	Classification Regulation:	21 CFR, Part 892.5840
	Classification Name:	Radiation Therapy Planning System
	Classification Panel:	Radiology
	Device Class:	Class II
	Product Code:	MUJ (System, planning, radiation therapy treatment)

Device description:

MRCAT brain is a software application to Ingenia, Ingenia Ambition, and Ingenia Elition MR systems. MRCAT brain is available to the customer as an option to Ingenia MR-RT package, which is a set of accessories for Ingenia systems.

Automated generation of MRCAT images takes place at the MR console of Ingenia. The embedded image post-processing runs in the background parallel to image acquisition. MRCAT algorithm enables automatic tissue characterization: Bones are segmented from mDixon in-phase and water images using machine learning based segmentation. Body outline is segmented using in-phase and water images. Tissues are then assigned a continuum of HU values depending on the fat and

water intensities of the voxels. The HU assignment provides MRCAT images with CT-like density information.

Indications for Use:

MRCAT Brain is a software add-on for Ingenia, Ingenia Ambition, and Ingenia Elition MR systems.

Intended Use:

MRCAT imaging is intended to provide the operator with information of tissue properties for radiation attenuation estimation purposes in photon external beam radiotherapy treatment planning.

Indications for use:

MRCAT brain is indicated for radiotherapy treatment planning for primary and metastatic brain tumor patients.

Fundamental Scientific Technology:

MRCAT brain functionality is implemented as a software plug-in for the MR main software and it contains the following main features:

1) Automatic post-processing tool delivering MRCAT images
2) Examcard with mDixon imaging protocol
3) DICOM export of MRCAT image.

<u>MRCAT Image Generation</u>

MRCAT images are generated with an ExamCard post-processing step, which uses the images from the previous mDixon scan.

The post-processing logic takes care of launching MRCAT algorithm executable calculating a new 3D MRCAT image. The post-processing is started once the acquired mDixon MR images have been reconstructed. The first step of MRCAT generation is to pre-process the images to ensure that the MRCAT source images have consistent intensities. The intensity normalized images are then used as input in a convolutional neural network (CNN). The CNN is trained using matched pairs of CT and MRCAT source images. The training of the CNN is locked and is not adapted during use. The output of the CNN is post-processed to create images in CT values. The generated MRCAT images are checked for correctness to ensure validity of the generated MRCAT for radiation treatment. The sanity checks ensure that the imaging field of view has been positioned correctly and that the MRCAT body outline matches that of the MR. The HU values for the

MRCAT brain are calibrated using registered CT images. Once the process is running, post-processing logic exchanges information with the algorithm:

- Image source data to algorithm, and image output data back to the post-processing step
- Progress notifications
- Error and warning notifications

The 3D MRCAT image from the post-processing step is stored into the MR image database.

mDIXON scan

A T1-weighted Fast Field Echo (FFE) 3D mDixon dual echo imaging protocol, with imaging parameters optimized for MRCAT image post-processing and for geometric accuracy, is delivered as a part of MRCAT brain option. The mDixon imaging sequence provides two image contrasts for the MRCAT algorithm: inphase and water images. MRCAT brain uses fixed parameters for the mDixon scan, only the image stack location is configurable. An mDixon imaging protocol, with imaging parameters optimized for MRCAT image post-processing and for geometric accuracy, is delivered as a part of MRCAT brain option. MRCAT brain uses fixed parameters for mDixon scan, only the image stack location is configurable.

DICOM Export

The MRCAT post-processing step stores the image data returned by the MRCAT algorithm into MR database.

MRCAT images can be exported in DICOM format enabling the use as primary images in the treatment planning systems

Hardware platform description

The new software extensions introduced by MRCAT brain run on the MR console of Ingenia.

Based on the information provided above, the **MRCAT brain** is considered substantially equivalent to the primary currently marketed and predicate device (K182888, April 30, 2019) in terms of fundamental scientific technology.

Summary of Non-Clinical Performance Data:

The **MRCAT brain** complies with the following international and FDA-recognized consensus standards:

International and FDA-recognized consensus standards:

- ANSI/AAMI ES60601-1: 2012, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-6:2010, Medical electrical equipment - Part 1-6: General requirements for safety - Collateral standard: Usability.
- IEC 60601-2-33:2015, Medical electrical equipment - Part 2-33: Particular requirements for the safety of magnetic resonance equipment for medical diagnosis.
- IEC 62304:2016, Medical device software - Software life-cycle processes
- IEC 62366-1:2015, Medical devices – Application of usability engineering to medical devices
- ISO 14971:2007, Medical devices – Application of risk management to medical devices

Non-Clinical verification and or validation tests have been performed with regards to the intended use, the technical claims, the requirement specifications and the risk management results.

Non Clinical verification and or validation test results demonstrate that the **MRCAT brain**:

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

Therefore, the **MRCAT brain** is substantially equivalent to the primary currently marketed and predicate device (K182888, April 30, 2019) in terms of safety and effectiveness. Detailed comparison for selected features is presented in Table 6-1 below.

Table 6-1 Comparison of the primary currently marketed and predicate device, MRCAT Pelvis versus the proposed MRCAT Brain			
Device	***MRCAT Pelvis***	***MRCAT Brain***	**Similarities and Differences**
Manufacturer	Philips Medical Systems MR Finland	Philips Medical Systems MR Finland	-
510(k) Number	K182888	K193109	N/A
Product Code	MUJ	MUJ	Identical
Regulation Number	892.5050	892.5050	Identical
Regulation Name	Accelerator, Linear, Medical	Accelerator, Linear, Medical	Identical
Intended use	MRCAT imaging is intended to provide the operator with information of tissue properties for radiation attenuation estimation purposes in photon external beam radiotherapy treatment planning.	MRCAT imaging is intended to provide the operator with information of tissue properties for radiation attenuation estimation purposes in photon external beam radiotherapy treatment planning.	Identical

Indications for use	MRCAT Pelvis is indicated for radiotherapy treatment planning of soft tissue cancers in the pelvic region.	*MRCAT Brain* is indicated for radiotherapy treatment planning for primary and metastatic brain tumor patients.	No significant difference. MRCAT Pelvis and *MRCAT* Brain are both indicated for radiotherapy treatment planning in a defined region. Brain tumors are soft tissue tumors.
Primary image dataset	MRCAT	MRCAT	No significant difference
Secondary image dataset	mDixon, MRI	mDixon, MRI	No significant difference MR images obtained in the same imaging session are inherently in the same frame of reference.

Registration between primary and secondary image datasets	Secondary mDixon MR image, source data to MRCAT, is inherently registered as part of MRCAT algorithm with MRCAT image, which simplifies workflow. Other MR images, like T2w and fiducial marker detection images are registered using tools available in RTP system	Secondary mDixon MR image, source data to MRCAT, is inherently registered as part of MRCAT algorithm with MRCAT image, which simplifies workflow. Other MR images, like T2w images are registered using tools available in RTP system	No significant difference Secondary MR images are obtained in the same imaging session reducing the possibility of patient motion between images.
Primary image density information	MRCAT image intensity information is provided in Hounsfield Unit (HU) values.	MRCAT image intensity information is provided in Hounsfield Unit (HU) values.	No significant difference. MRCAT Pelvis and MRCAT Brain both have continuous HU value approach.
Conversion from primary image to density values used in dose calculation	Primary image HU values are converted to densities through density table specific for the MRCAT.	Primary image HU values are converted to densities through density table specific for the MRCAT.	No significant difference MRCAT has specific density table that is used in a similar manner to CT specific density tables.
MRCAT algorithm	Bones are segmented from mDixon inphase and water images using model based	Bones are segmented from mDixon inphase and water images using machine	No significant difference Segmentation is done for both MRCAT

	segmentation. The segmented bones are the femurs, pelvic bones and lumbar vertebrae L5 and L1. Body outline is segmented using inphase and water images. Bones are assigned a continuum of HU values between dense cortical bone and light spongy bone depending on the fat and water intensities of the voxels. Soft tissue are assigned a continuum of HU values between fat and muscle tissue depending on the fat and water intensities of the voxels. The HU values for the *MRCAT* Pelvis are calibrated using registered CT images from several sites.	learning based segmentation. The segmented bones are in skull, upper C-spine and jaw. Body outline is segmented using inphase and water images. Bones are assigned a continuum of HU values between dense cortical bone and light spongy bone depending on the fat and water intensities of the voxels. Soft tissue are assigned a continuum of HU values depending on the fat and water intensities of the voxels. The HU values for the MRCAT *Brain* are calibrated using registered CT images from several sites. *MRCAT Brain* algorithm is fully trained before product release, after which the algorithm is locked.	Pelvis and *Brain* using the mDIXON image contrasts. HU value assignment is done based on mDixon image intensities. The models used are equivalent in relation to dose and positioning accuracy. Both algorithms are locked; they do not change after installation based on new data during the use.

Patient positioning	Ingenia MR-RT with *MRCAT Pelvis* supports MR Only simulation with relative patient marking. Patient positioning in the treatment machine must be checked either with cone beam computed tomography (CBCT) or plain radiographs by registering bone structures or internal fiducial markers.	Ingenia MR-RT with *MRCAT Brain* supports MR Only simulation with relative patient marking. Patient positioning in the treatment machine must be checked either with cone beam computed tomography (CBCT) or plain radiographs by registering bone structures.	No significant difference The visibility of bone structures is equivalent for both products. Internal markers are not used for brain tumors.

Dose accuracy	The simulated dose based on MRCAT images shall not differ in 95% of prostate cancer patients (gamma analysis criterion 3%/3mm realized in 99% of voxels within the PTV or exceeding 75% of the maximum dose) when compared with CT based plan. The average simulated dose based on MRCAT images shall not deviate more than 10% for voxels exceeding 5Gy in 99% of the indicated patients in the volume of sensitive organs when compared with CT based plan.	The simulated dose based on MRCAT Brain images shall not differ in 95% of the indicated patients (gamma analysis criterion 2%/2mm realized in 98% of voxels within the PTV or exceeding 75% of the maximum dose) when compared with CT-based plan. The average simulated dose based on MRCAT Brain shall not deviate more than 5% or 1 Gy, which ever is greater, in 99% of the indicated patients in the volume of sensitive organs when compared with CT based plan.	No significant difference. The same dose evaluation methodology is used for both products. The criteria are selected based on the needs of the application.
Geometric accuracy	MRCAT accuracy: ± 1 mm accuracy: 200 mm diameter sphere ± 5 mm accuracy: 500 mm diameter sphere (limited in the bore direction by +/- 160 mm from the z=0 mm plane)	MRCAT accuracy: ± 1 mm accuracy: 200 mm diameter sphere ± 5 mm accuracy: 500 mm diameter sphere (limited in the bore direction by +/- 160 mm from the z=0 mm plane)	No significant difference

MRCAT source imaging sequence	mDIXON 3D scan with acquired voxel size of 1.40/1.40/1.40 mm, and bandwidth/pixel 430Hz (1.5T) or 860Hz (3T). Most scanning parameters locked	mDIXON 3D scan with acquired voxel size of 1.10/1.10/1.40 mm (1.5 T) and 1.1/1.1/1.1 mm (3T), and bandwidth/pixel 481Hz (1.5T) or 868Hz (3T). Most scanning parameters locked	No significant difference Especially, the sensitivity to B0 induced distortion in the read direction is about 0.2 mm/ppm in both MRCAT Pelvis and *MRCAT Brain*. In both solutions the essential parameters are locked to avoid user errors potentially affecting the accuracy and reliability of the method.
DICOM RT export	yes	yes	No significant difference

Summary of Clinical Data:

The robustness of the MRCAT brain algorithm for producing equivalent dose plans to CT using gamma analysis with criterion of 1%/1mm is shown by post-processing MRCAT images from patients, and calculating dose using the MRCAT images.

In summary, the MRCAT brain images are spatially accurate radiation attenuation estimates that can aid in the EBRT planning of primary and metastatic brain tumors.

Substantial Equivalence Conclusion:

The **MRCAT brain** is substantially equivalent to the primary currently marketed and predicate device (K182888, April 30, 2019) in terms of design features, fundamental scientific technology, indications for use, and safety and effectiveness. Additionally, substantial equivalence was

demonstrated with non-clinical performance (verification and validation) tests, which complied with the requirements specified in the international and FDA-recognized consensus standards, IEC 62304, IEC 62366-1 and ISO 14971. The results of these tests demonstrate that **MRCAT brain** met the acceptance criteria and is adequate for this intended use.