



April 5, 2022

Philips Oy  
% Anne-Sophie Glantenay  
Sr. Regulatory Affairs Specialist  
Äyritie 4  
Vantaa, 01510  
Finland

Re: K214081

Trade/Device Name: MRCAT Head & Neck  
Regulation Number: 21 CFR 892.5050  
Regulation Name: Medical Charged-Particle Radiation Therapy System  
Regulatory Class: Class II  
Product Code: MUJ  
Dated: December 23, 2021  
Received: December 27, 2021

Dear Anne-Sophie Glantenay:

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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Julie M. Sullivan, PhD  
Branch Chief  
Nuclear Medicine and Radiation Therapy Branch  
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

## Indications for Use

510(k) Number (if known)  
K214081

Device Name  
MRCAT Head & Neck

Indications for Use (Describe)

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.

Indication for use:

MRCAT Head and Neck is indicated for radiotherapy treatment planning for patients with soft tissue tumors in the Head and Neck region.

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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## 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** April 05, 2022

**Prepared:**

**Manufacturer:** Philips Oy  
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01510 Vantaa, Finland

Establishment Registration Number: 9680194

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**Device Name:** MRCAT Head & Neck

**Classification:** Classification Name: Medical charged-particle radiation therapy system (accessory for)  
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 Brain  
Manufacturer: Philips Oy

510(k) Clearance: K193109 (January 24, 2020)  
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 (Cleveland), Inc.  
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 Head & Neck is a software application to Ingenia, Ingenia Ambition, and Ingenia Elition MR systems. MRCAT Head & Neck 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 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 Head and Neck is indicated for radiotherapy treatment planning for patients with soft tissue tumors in the Head and Neck region.

**Fundamental Scientific Technology:**

MRCAT Head and Neck 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.

MRCAT Image Generation

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 Head and Neck 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 Head and Neck option. The mDixon imaging sequence provides two image contrasts for the MRCAT algorithm: inphase and water images. MRCAT Head and Neck 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 Head and Neck option. MRCAT Head and Neck 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 Head and Neck run on the MR console of Ingenia.

Based on the information provided above, the **MRCAT Head and Neck** is considered substantially equivalent to the primary currently marketed and predicate device (K193109, January 24, 2020) in terms of fundamental scientific technology.

Comparison of technological characteristics with the predicate device:

<b>Table 1</b> <b>Comparison of the primary currently marketed and predicate device, MRCAT Brain versus the proposed MRCAT Head &amp; Neck</b>			
Device	<i>MRCAT Brain</i>	<i>MRCAT Head &amp; Neck</i>	Similarities and Differences
<b>Manufacturer</b>	Philips Oy	Philips Oy	-
<b>510(k) Number</b>	K193109	-	-
<b>Product Code</b>	MUJ	MUJ	Identical
<b>Regulation Number</b>	892.5050	892.5050	Identical
<b>Regulation Name</b>	Accelerator, Linear, Medical	Accelerator, Linear, Medical	Identical
<b>Intended use</b>	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
<b>Indications for use</b>	MRCAT Brain is indicated for radiotherapy treatment planning for primary and metastatic brain tumor patients.	MRCAT Head and Neck is indicated for radiotherapy treatment planning for patients with soft tissue tumors in the Head and Neck region	No significant difference.  MRCAT Brain and <i>MRCAT Head &amp; Neck</i> are both indicated for radiotherapy treatment planning in a defined region.  Brain tumors are soft tissue tumors.



<b>Primary image dataset</b>	MRCAT	MRCAT	Identical
<b>Secondary image dataset</b>	mDixon, MRI	mDixon, MRI	Identical MR images obtained in the same imaging session are inherently in the same frame of reference.
<b>Registration between primary and secondary image datasets</b>	<p>Secondary mDixon MR image, source data to MRCAT, is inherently registered as part of MRCAT algorithm with MRCAT image, which simplifies workflow.</p> <p>Other MR images, like T2w and fiducial marker detection images are registered using tools available in RTP system</p>	<p>Secondary mDixon MR image, source data to MRCAT, is inherently registered as part of MRCAT algorithm with MRCAT image, which simplifies workflow.</p> <p>Other MR images, like T2w images are registered using tools available in RTP system</p>	<p>No significant difference</p> <p>Secondary MR images are obtained in the same imaging session reducing the possibility of patient motion between images.</p>
<b>Primary image density information</b>	MRCAT image intensity information is provided in Hounsfield Unit (HU) values.	MRCAT image intensity information is provided in Hounsfield Unit (HU) values.	<p>Identical.</p> <p>MRCAT Brain and MRCAT Head &amp; Neck both have continuous HU value approach.</p>

<p><b>Conversion from primary image to density values used in dose calculation</b></p>	<p>Primary image HU values are converted to densities through density table specific for the MRCAT.</p>	<p>Primary image HU values are converted to densities through density table specific for the MRCAT.</p>	<p>No significant difference</p> <p>MRCAT has specific density table that is used in a similar manner to CT specific density tables.</p>
<p><b>MRCAT algorithm</b></p>	<p>Bones are segmented from mDixon in-phase and water images using machine learning based segmentation. The segmented bones are in skull, upper C-spine and jaw.</p> <p>Body outline is segmented using in-phase and water images.</p> <p>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.</p> <p>Soft tissue are assigned a continuum of HU values depending on the fat and water intensities of the voxels.</p> <p>The HU values for the <i>MRCAT Brain</i> are calibrated using registered CT images from several sites.</p> <p><i>MRCAT Brain</i> algorithm is fully trained before product release, after</p>	<p>Bones are segmented from mDixon in-phase and water images using machine learning based segmentation. The segmented bones are in skull, C-spine, jaw, and shoulder girdle.</p> <p>Body outline is segmented using in-phase and water images.</p> <p>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.</p> <p>Soft tissue are assigned a continuum of HU values depending on the fat and water intensities of the voxels.</p> <p>The HU values for the <i>MRCAT Head &amp; Neck</i> are calibrated using</p>	<p>No significant difference</p> <p>Segmentation is done for both MRCAT Brain and MRCAT Head &amp; Neck using the mDIXON image contrasts. HU value assignment is done based on mDixon image intensities.</p> <p>The models used are equivalent in relation to dose and positioning accuracy.</p> <p>Both algorithms are locked; they do not change after installation based on new data during the use.</p>

	<p>which the algorithm is locked.</p>	<p>registered CT images from several sites.</p> <p><i>MRCAT Head &amp; Neck</i> algorithm is fully trained before product release, after which the algorithm is locked.</p>	
<p><b>Patient positioning</b></p>	<p>Ingenia MR-RT with <i>MRCAT Brain</i> supports MR Only simulation with relative patient marking.</p> <p>Patient positioning in the treatment machine must be checked either with cone beam computed tomography (CBCT) or plain radiographs by registering bone structures.</p>	<p>Ingenia MR-RT with <i>MRCAT Head &amp; Neck</i> supports MR Only simulation with relative patient marking.</p> <p>Patient positioning in the treatment machine must be checked either with cone beam computed tomography (CBCT) or plain radiographs by registering bone structures.</p>	<p>No significant difference</p> <p>The visibility of bone structures is equivalent for both products.</p>

<p><b>Dose accuracy</b></p>	<p>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.</p> <p>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.</p>	<p>The simulated dose based on MRCAT Head &amp; Neck 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.</p> <p>The average simulated dose based on MRCAT Head &amp; Neck 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.</p>	<p>Identical</p> <p>The same dose evaluation methodology is used for both products. The criteria are selected based on the needs of the application.</p>
<p><b>Geometric accuracy</b></p>	<p>MRCAT accuracy:</p> <p>± 1 mm accuracy: 200 mm diameter sphere</p> <p>± 2 mm accuracy: 400 mm diameter sphere (limited in the bore direction by +/- 160 mm from the z=0 mm plane)</p> <p>± 5 mm accuracy: 500 mm diameter sphere (limited in the bore direction by +/- 160 mm from the z=0 mm plane)</p>	<p>MRCAT accuracy:</p> <p>± 1 mm accuracy: 200 mm diameter sphere</p> <p>± 2 mm accuracy: 400 mm diameter sphere (limited in the bore direction by +/- 160 mm from the z=0 mm plane)</p> <p>± 5 mm accuracy: 500 mm diameter sphere (limited in the bore direction by +/- 160 mm from the z=0 mm plane)</p>	<p>Identical</p>

<b>MRCAT source imaging sequence</b>	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	mDIXON 3D scan with acquired voxel size of 1.2/1.2/1.2 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  In both solutions the essential parameters are locked to avoid user errors potentially affecting the accuracy and reliability of the method. The voxel sizes do not differ significantly.
<b>DICOM RT export</b>	yes	yes	Identical

**Summary of Non-Clinical Performance Data:**

The **MRCAT Head and Neck** 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 62366-1:2020, Medical devices – Application of usability engineering to medical devices
- ISO 14971:2019, 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 Head and Neck**:

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

Therefore, the **MRCAT Head and Neck** is substantially equivalent to the primary currently marketed and predicate device (K193109, January 24, 2020) in terms of safety and effectiveness.

**Summary of Clinical Data:**

The resulting dose accuracy for MRCAT Head and Neck is similar to CT. The PTV dose differences obtained when using MRCAT in place of CT are well below 1% with a very small bias, and therefore clinically insignificant.

The dose analysis was further expanded with artificial PTV analysis, using PTVs that were automatically placed around the head and neck region. The results for the artificial PTVs agreed well with the clinical plan results and strengthen the conclusion that MRCAT provides accurate dose calculations for the head and neck region.

In summary, the MRCAT Head and Neck images are spatially accurate radiation attenuation estimates that can aid in the EBRT planning of soft tissue tumors in the head and neck region.

**Substantial Equivalence Conclusion:**

The **MRCAT Head and Neck** is substantially equivalent to the primary currently marketed and predicate device (K193109, January 24, 2020) 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 Head and Neck** met the acceptance criteria and is adequate for this intended use.