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

April 30, 2019

Re: K182888
Trade/Device Name: MRCAT Pelvis
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: Class II
Product Code: MUJ
Dated: March 22, 2019
Received: April 1, 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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)*
K182888

Device Name
MRCAT Pelvis

Indications for Use *(Describe)*

MRCAT Pelvis is a software add-on for Ingenia 1.5T and 3.0T 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 Pelvis is indicated for radiotherapy treatment planning of soft tissue cancers in the pelvic 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

In accordance with 21 CFR 807.92 the following summary of information is provided:

Owner/Contact/Date (807.92(a)(1):

Date:	March 22, 2019
Owner/Submitter:	Philips Medical Systems MR Finland Äyritie 4 01510 Vantaa FINLAND Phone: +358-9-615 800 Fax: +358-9-3487 2406
Primary Contact Person:	Janne Marvola Regulatory Engineer Philips Medical Systems MR Finland Phone: +358-40-126 1214 Fax: +358-9-3487 2406 E-mail: regulatory.mr.therapy@philips.com
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Device names (807.92(a)(2)):

Trade Name:	*MRCAT Pelvis*
Classification:	Class II
Regulatory Section:	21 CFR 892.5050
Product Code:	MUJ

Predicate Device(s) (807.92(a)(3)::)	K151435 MRCAT (primary) K013644 AcQPlan 5.0 (reference device)
Device Description (807.92(a)(4))::)	*MRCAT Pelvis* is a software application to Ingenia 1.5T and 3T MR systems. *MRCAT Pelvis* 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 algorithms enable automatic tissue characterization of five tissue types; air, fat, water-rich tissue, spongy bone and compact bone. Subsequent density assignment provides MRCAT images with CT-like density information.
Intended Use: (807.92(a)(5):	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 Pelvis is indicated for radiotherapy treatment planning of soft tissue cancers in the pelvic region.
Technology (807.92(a)(6))::)	*MRCAT Pelvis* 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 algorithm enables model based segmentation of bones and soft tissues. Subsequent density assignment provides MRCAT images with CT-like density information. 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

An mDixon imaging protocol, with imaging parameters optimized for MRCAT image post-processing and for geometric accuracy, is delivered as a part of MRCAT option. MRCAT 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

MRCAT Pelvis does not require any change of the hardware platform of Ingenia scanners. The new software extensions introduced by *MRCAT Pelvis* run on the MR console of Ingenia.

Determination of Substantial Equivalence, non-clinical (807.92(b)(1)):

Summary of Non-Clinical Tests:

The MRCAT software complies with voluntary standards as detailed below. The following quality assurance measures were applied to the development of the system:

- Risk Analysis
- Testing on unit level (Subsystem verification)
- Integration testing (System verification)
- Final acceptance testing (Validation)
- Performance testing (Verification)
- Safety testing (Verification)

The MRCAT software was designed and tested for compliance to the following standards:

1. ANSI/AAMI ES60601-1: 2012, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance – Third Edition
2. IEC 60601-1-6:2006, Medical electrical equipment - Part 1-6: General requirements for safety - Collateral standard: Usability.
3. IEC 60601-2-33:2015, Medical electrical equipment - Part 2-33: Particular requirements for the safety of magnetic resonance equipment for medical diagnosis.
4. IEC 62304:2006, Medical device software - Software life-cycle processes
5. ISO 14971:2007, Medical devices. Application of risk management to medical devices

All requirements are met for the *MRCAT Pelvis* application.

The conclusion from these reports is:

All the tests performed for *MRCAT Pelvis* software were successful. All defects have been analyzed and are confirmed that they are not safety defects and will not cause any hazardous situation on using this application.

Clinical (807.92(b)(2)):

Summary of Clinical Tests:

The robustness of the *MRCAT Pelvis* algorithm for producing equivalent dose plans to CT using gamma analysis with criterion of 3%/3mm is shown by post-processing MRCAT images from patients, and calculating dose using the MRCAT images.

In summary, the *MRCAT Pelvis* images are spatially accurate radiation attenuation estimates that can aid in the EBRT planning of pelvic soft tissue cancers.

Conclusion (807.92(b)(3))::

MRCAT Pelvis software is a tool to provide the operator with information of tissue properties for radiation attenuation estimation purposes in photon external beam radiotherapy treatment planning for pelvic cancer patients.

It is the opinion of Philips Medical Systems MR Finland that the *MRCAT Pelvis* software option for Philips Ingenia MR scanners is substantially equivalent and raises no new issues of safety or effectiveness compared to the primary predicate Philips MRCAT, K151435 cleared by FDA on February 25, 2016 and the reference device AcQPlan 5.0, K013644, cleared by FDA on September 12, 2002.