Spectronic Medical AB
℅ Per Bruhn
Manager of Quality Assurance and Regulatory Affairs
Karbingatan 36
Helsingborg, 25467
SWEDEN

Re: K211841
Trade/Device Name: MRI Planner
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: Class II
Product Code: MUJ, QKB
Dated: July 22, 2022
Received: July 25, 2022

Dear Per Bruhn:

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

Julie Sullivan, Ph.D.
Assistant Director
DHT8C: Division of Radiological Imaging
and Radiation Therapy Devices
OHT8: Office of 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: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K211841

Device Name

MRI Planner

Indications for Use *(Describe)*

MRI Planner is a software-only medical device intended for use by trained radiation oncologists, dosimetrists and physicists to process images from MRI systems to

1) provide the operator with information of tissue properties for radiation attenuation estimation purposes in photon external beam radiotherapy treatment planning, and to

2) derive contours for input to radiation treatment planning by assisting in localization and definition of healthy anatomical structures.

MRI Planner is not intended to automatically contour tumors or tumor clinical target volumes.

MRI Planner is indicated for radiotherapy planning of adult patients for primary and metastatic cancers in the brain and head-neck regions, as well as soft tissue cancers in the pelvic region.

MRI Planner generates synthetic CT images for radiation attenuation estimation purposes for the pelvis, brain and head-neck regions only. MRI Planner generates automatically derived contours of the bladder, colon and femoral heads, for prostate cancer patients only.

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.

1. 510(k) Summary

K211841

The following summary of the present 510(k) submission is provided:

Date Prepared	August 25, 2022
Contact details	Spectronic Medical AB Karbingatan 36 254 67 Helsingborg SWEDEN
Contact Person	Per Bruhn Manager of Quality Assurance and Regulatory Affairs Spectronic Medical AB Tel: +46 735 116042 Email: per.bruhn@spectronic.se
Device trade name: **Common Name:** **Classification Regulation:** **Classification Name:** **Panel:** **Classification:** **Product Code:**	MRI Planner MRI Planner 21 CFR 892.5050 Medical charged-particle radiation therapy system Radiology Class II MUJ, QKB
Predicate Device	Device name: MRCAT Brain Manufacturer: Philips Medical Systems MR Finland 510(k) Clearance: K193109 Classification Regulation: 21 CFR 892.5050 Classification Name: Medical charged-particle radiation therapy system Classification Panel: Radiology Device Class: II Product Code: MUJ
Reference Devices	Reference Device 1: Device name: MRCAT Pelvis Manufacturer: Philips Medical Systems MR Finland 510(k) Clearance: K182888 Classification Regulation: 21 CFR 892.5050 Classification Name: Medical charged-particle radiation therapy system Classification Panel: Radiology Device Class: II Product Code: MUJ Reference Device 2: Device name: Limbus Contour Manufacturer: Limbus AI, Inc. 510(k) Clearance: K201232 Classification Regulation: 21 CFR 892.2050 Classification Name: Medical image management and processing system Classification Panel: Radiology Device Class: II Product Code: LLZ
Device Description Summary	The product MRI Planner is a stand-alone software providing information to the treatment planning process prior to radiotherapy. Based on a DICOM

	MR image stack, the software generates synthetic CT images that can be used for attenuation calculations in radiotherapy treatment planning for the pelvis, brain and head-neck regions. In addition, the software also generates contours of anatomical structures in the MR image stack, to be used as a starting point for the manual delineation work required in radiotherapy treatment planning. Contours are generated for prostate cancer patients only (bladder, colon and femoral heads). MRI Planner utilizes pre-trained machine learning models to perform both the conversion to synthetic CT and the automated structure contouring. The models for synthetic CT generation was trained using a dataset comprising MR and CT images for 244 patients acquired in the treatment position at four hospitals. The model for prostate cancer patient auto contouring was trained using a dataset comprising MR images for 175 patients acquired in the treatment position at four hospitals, together with in-house generated expert manual contours. MRI Planner does not display or store DICOM images. The user is advised to use existing softwares for radiotherapy treatment planning to display and modify generated images and contours. MRI Planner runs on a standard x86-64 compatible system with a CUDA capable NVIDIA GPU and requires Ubuntu Linux 18.04 operating system.
Indications For Use	MRI Planner is a software-only medical device intended for use by trained radiation oncologists, dosimetrists and physicists to process images from MRI systems to 1) provide the operator with information of tissue properties for radiation attenuation estimation purposes in photon external beam radiotherapy treatment planning, and to 2) derive contours for input to radiation treatment planning by assisting in localization and definition of healthy anatomical structures. MRI Planner is not intended to automatically contour tumors or tumor clinical target volumes. MRI Planner is indicated for radiotherapy planning of adult patients for primary and metastatic cancers in the brain and head-neck regions, as well as soft tissue cancers in the pelvis region. MRI Planner generates synthetic CT images for radiation attenuation estimation purposes for the pelvis, brain and head-neck regions only. MRI Planner generates automatically derived contours of the bladder, colon and femoral heads, for prostate cancer patients only.
Indications for Use comparison	MRI Planner provides the indications for use of the Predicate Device. The Predicate Device has the intended use to provide the operator with information of tissue properties for radiation attenuation estimation purposes in photon external beam radiotherapy treatment planning. MRI Planner includes the intended use of the Predicate Device, as it provides the operator with information of tissue properties for radiation attenuation estimation purposes in photon external beam radiotherapy treatment planning. Additionally, it provides the functionality of auto contouring, which is not believed to raise additional safety concerns. As such, the indications for use of MRI Planner does not raise any

	additional or different concerns regarding safety or effectiveness as compared to the Predicate Device.
Technological comparison	Both MRI Planner and the Predicate Device are machine learning based. Reference Device 1 was used as predicate device for the Predicate Device and is therefore also technologically equivalent. Both the Predicate Device and Reference Device 1 generates similar outputs as MRI Planner in the form of synthetic CT images. Since MRI Planner has similar technological characteristics as both the Predicate Device and Reference Device 1 with regard to synthetic CT generation, no differences in risk have been identified between the products. Both MRI Planner and Reference Device 2 use pre-trained machine learning models to derive contours. Since MRI Planner has similar technological characteristics as Reference Device 2 with regard to deriving contours, no differences in risk have been identified between the products.
Summary of performance testing	**Dose accuracy bench test** The conducted bench tests evaluate the dosimetric equivalence of MRI Planner generated synthetic CT (sCT) and conventional CT. Dosimetric agreement was evaluated by comparing mean doses to target and non-target volumes as well as by means of gamma evaluation. The non-target sCT-CT dose difference was evaluated by computing the mean dose difference in all sub-volumes of the dose matrix not overlapping the target. The acceptance criteria was that 99% of cases should have no sub-volumes with an sCT-CT dose difference in excess of 1.0 Gy or 5% of the CT-dose. Two variations of gamma evaluation were conducted; one focusing on the high dose area (cut off at 75% of the maximum dose) and the other considering also the medium dose regions (cut off at 25% of the maximum dose). In the high dose gamma a 3%/3mm criteria was used for the pelvic and head-neck anatomical regions, while a 2%/2mm criteria was used for brain cases. The gamma index passing rate requirement was 99% for pelvis and head-neck, and 98% for brain. In the medium dose range gamma evaluation the stricter 2%/2mm criteria was used for all anatomical regions, while requiring a 99% gamma index passing rate. The average sCT-CT mean target dose difference was found to be 0.02% ± 0.31% and -0.02% ± 0.25% for the anatomical regions pelvis, and head-neck and brain, respectively. No cases displayed any sub-volumes with sCT-CT dose differences in excess of 5% or 1.0 Gy. At least 95% of cases met the passing criteria across all gamma evaluations and anatomical regions. In the high dose gamma evaluation, 100.0% of cases passed the individual passing rate criterion for all anatomical regions, while the average gamma index passing rate was 99.9%, 99.8% and 99.8% for pelvis, head neck and brain, respectively. In the medium dose gamma evaluation, 98.3% and 100.0% of cases passed the individual passing rate criterion for pelvis, and head-neck and brain, respectively, while the average gamma index passing rate was 99.7%, 99.5% and 99.9% for pelvis, head neck and brain, respectively. Dosimetric bench test data for pelvis consisted of MR (T2w) and CT images for 58 unique pelvis cancer patients acquired in the treatment position at six different hospitals. Patient distribution was 16% female and 84% male, age range 51-88 years, 41% of patient images were acquired in the US and 59% outside the US.

	Dosimetric bench test data for head-neck-brain consisted of MR (T1-Dixon) and CT images for 75 unique head-neck-brain cancer patients acquired in the treatment position at four different hospitals. Patient distribution was 39% female and 64% male, age range 41-85 years, 55% of patient images were acquired in the US and 45% outside the US. MRI data was acquired at six different MRI scanner models, from two different vendors, with field strengths of 1.5T and 3T. **Auto contouring bench test** The conducted bench tests evaluates the automatically generated prostate patient delineations (of bladder, colon and femoral heads) against manual delineations, using two common metrics; Dice score (DSC) and 95% Hausdorff distance (HD). The average DSC was found to be 0.95 ± 0.03, 0.90 ± 0.04 and 0.96 ± 0.01 for bladder, colon and femoral head delineations, respectively. The average 95% HD was found to be 2.69 ± 1.82, 4.96 ± 3.91 and 2.04 ± 0.49 for bladder, colon and femoral head delineations, respectively. Auto contouring bench test data for prostate cancer patients consisted of MR (T2w) images for 51 unique male prostate cancer patients acquired in the treatment position at five different hospitals, together with manually generated delineations of bladder, colon and femoral heads. Patient age range was 51-88 years, 39% of patient images were acquired in the US and 61% outside the US. Manual delineations were generated by two expert truthers using the consensus approach, based on US clinical guidelines. The manual delineations for the bench tests were generated at a separate time from the generation of the training dataset. The truthers were involved in the development of the product and the generation of the training dataset, but not in the training and tuning of the segmentation model. Both truthers were employed by the manufacturer at the time of performing the manual delineations for the bench test.
Non-clinical test summary and conclusion	MRI Planner complies with the following international and FDA-recognized consensus standards: ISO 14971 Second edition 2007-03-01 Medical devices – Application of risk management to medical devices IEC 62304 Edition 1.1 2015-06 CONSOLIDATED VERSION Medical device software – Software life cycle processes IEC 62366-1:2015 Medical devices – Part 1: Application of usability engineering to medical devices IEC 82304-1 Edition 1.0 2016-10 Health software – Part 1: General requirements for product safety Non-clinical verification and 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 validation test results demonstrate that MRI Planner: • Complies with the aforementioned international and FDA-recognized consensus standards • Meets all acceptance criteria as described in the product test description and is adequate for its intended use. In addition, non-clinical bench tests have been performed to investigate the performance of MRI Planner against the Predicate Device. The bench tests demonstrate that MRI Planner performs comparably to the Predicate Device. Taking all of the above into account, Spectronic Medical believes that MRI Planner is as safe and effective as the Predicate Device, and is therefore substantially equivalent.