Brainlab AG
% Sadwini Suresh
QM Consultant, Regulatory Affairs
Olof-Palme-Str. 9
Munchen, BY 81829
GERMANY

March 14, 2023

Re: K223279/S001
Trade/Device Name: RT Elements (4.0)
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical Charged-Particle Radiation Therapy System
Regulatory Class: Class II
Product Code: MUJ
Dated: February 13, 2023
Received: February 13, 2023

Dear Sadwini Suresh:

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,

Lora D. Weidner -S

Digitally signed by Lora D. Weidner -S
Date: 2023.03.14 19:25:04 -04'00'

Lora D. Weidner, 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.

510(k) Number *(if known)*
K223279

Device Name
RT Elements 4.0

Indications for Use *(Describe)*
The device is intended for radiation treatment planning for use in stereotactic, conformal, computer planned, Linac based radiation treatment and indicated for cranial, head and neck and extracranial lesions.

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

March 13, 2023

General Information	
Manufacturer	Brainlab AG; Olof-Palme Str.9; 81829, Munich, Germany
Establishment Registration	8043933
Trade Names	RT Elements 4.0
Classification Name	Medical charged-particle radiation therapy system
Product Code	MUJ
Regulation Number	892.5050
Regulatory Class	II
Panel	Radiology
Predicate Device	K203681 RT Elements, Cranial SRS w/ Cones, Multiple Brain Mets SRS, Cranial SRS, Spine SRS, RT QA, Dose Review
Contact Information	
Primary Contact	Sadwini Suresh QM Consultant Regulatory Affairs Phone: +49 89 99 15 68 0 Email: regulatory.affairs@brainlab.com
Alternate Contact	Chiara Cunico Senior Manager Regulatory Affairs Phone: +49 89 99 15 68 0 Email: chiara.cunico@brainlab.com

1. Indication for Use

The device is intended for radiation treatment planning for use in stereotactic, conformal, computer planned, Linac based radiation treatment and indicated for cranial, head and neck and extracranial lesions.

2. Device Description

RT Elements are computed-based software applications for radiation therapy treatment planning and dose optimization for linac-based conformal radiation treatments, i.e. stereotactic radiosurgery (SRS), fractionated stereotactic radiotherapy (SRT) or stereotactic ablative radiotherapy (SABR), also known as stereotactic body radiation therapy (SBRT) for use in stereotactic, conformal, computer planned, Linac based radiation treatment of cranial, head and neck, and extracranial lesions.

The following applications are included in RT Elements 4.0:

- Multiple Brain Mets SRS
- Cranial SRS
- Spine SRS
- Cranial SRS w/ Cones
- RT QA

- Dose Review
- Retreatment Review

3. Substantial Equivalence

The Subject Device has similar intended use and technological features as the predicate device. An overview of the similarities and differences can be found in the tables below:

Topic/ Feature	Predicate Device (RT Elements 3.0 K203681)	Subject Device (RT Elements 4.0)	Comment
Indications for use	The RT Elements are applications for radiation treatment planning for use in stereotactic, conformal, computer planned, Linac based radiation treatment of cranial, head and neck and extracranial lesions. The **Cranial SRS w/ Cones** application as one RT Element provides planning and display for functional diseases (e.g. trigeminal neuralgia) or cranial lesion radiation treatment. The **Multiple Brain Mets SRS** application as one RT Element provides optimized planning and display for cranial multi-metastases radiation treatment planning. The **Cranial SRS** application as one RT Element provides optimized planning and display for cranial radiation treatment planning. The **Spine SRS** application as one RT Element provides optimized planning and display for single spine metastases. The **RT QA** application as one RT Element contains features for patient specific quality assurance. Use RT QA to recalculate patient treatment plans on a phantom to verify that the patient treatment plan fulfills the planning requirements. The **Dose Review** application as one RT Element contains features for review of isodose lines, review of DVHs, dose comparison and dose summation.	The device is intended for radiation treatment planning for use in stereotactic, conformal, computer planned, Linac based radiation treatment and indicated for cranial, head and neck and extracranial lesions.	The Subject Device has similar indications for use as the Predicate Device. The Subject Device has a revised generic indications for use statement.

Topic/ Feature	Predicate Device (RT Elements 3.0 K203681)	Subject Device (RT Elements 4.0)	Comment
Applications/Elements Included	• Multiple Brain Mets SRS • Cranial SRS • Spine SRS • Cranial SRS w/ Cones • RT QA • Dose Review	• Multiple Brain Mets SRS • Cranial SRS • Spine SRS • Cranial SRS w/ Cones • RT QA • Dose Review • Brain Mets Retreatment Review	The Subject device has the same Elements included as the Predicate Device. Additionally, RT Elements 4.0 has the new Brain Mets Retreatment Review Element.
Supported Operating Systems	• Windows 10 Enterprise 1507 • Windows 10 Enterprise 1607 • Windows 10 Enterprise 1809 • Windows Server 2012 R2 64-bit • Windows Server 2016 • Windows Server 2019	• Windows 10 Enterprise 1507 • Windows 10 Enterprise 1607 • Windows 10 Enterprise 1809 • Windows Server 2012 R2 64-bit • Windows Server 2016 • Windows Server 2019	The Subject Device supports the same operating systems as the Predicate Device.
Supported Collimators	• Multileaf Collimators Circular Conical Collimators	• Multileaf Collimators Circular Conical Collimators	The Subject Device supports the same collimator types as the Predicate Device.
GUI Technology	• WPF	• WPF • html5	The Subject Device has a similar GUI technology as the Predicate Device. Parts of the subject device were transmitted to html5.
Dose Calculation Accuracy	Pencil Beam/Monte Carlo: better than 3% Circular Cone: 1%/1mm	Pencil Beam/Monte Carlo: better than 3% Circular Cone: 1%/1mm	The dose calculation in the Subject Device is the same as in the Predicate Device.
Support of Metal Implants	No support of metal implants available.	It is possible to calculate treatment plans for targets with metal implants in the surrounding of the lesion, accounting for a selected material of the implant during dose calculation. It is also possible to define the material of implant objects from a given list to be used for tissue model generation	With the Subject Device it is possible to consider metal implants during treatment planning especially for spinal metastasis.

Topic/ Feature	Predicate Device (RT Elements 3.0 K203681)	Subject Device (RT Elements 4.0)	Comment
Treatment Time Bar	No time bar available.	All objects that are listed in the time bar are shown on the newest MR in the ACS view and are visualized in the 3D view. The metastases are color-coded to provide an overview of when the metastases were treated.	A new feature coming with the new Brain Mets Retreatment Element. It supports the user in decision making. No new data is generated by this feature. Instead it gives the user a better overview of different treatment data

4. Performance Data

Verification

Software Verification:
Software verification was performed, verifying the software requirements through integration tests, and unit tests. Incremental test strategies have been set up after verification of the first release candidate for changes with limited scope. In this case, an impact analysis of the modifications is performed and tests to be performed are identified and planned correspondingly. That means, not all tests have to be performed but only a subset, as some of the previous tests are not affected by the change and remain therefore valid.
Software verification verifies all specifications, including SOUP items and cybersecurity.
For newly added components, interoperability tests were carried out, in addition to the individual component verification.

Bench Testing
In addition to the routine software verification, the following tests were carried out:

Usability Evaluation:
Summative and Formative Usability Evaluation was carried out specifically for the Retreatment Review Element which is a new application.

Clinical Evaluation:
Clinical Evaluation was carried out as a part of the design validation process.
Based on the results gathered during the validation process, it was concluded that the device meets the safety and performance requirements and is safe and effective for its intended use as compared to the predicate device.

5. Conclusion

Verification and validation activities carried out established that the set requirements were met and that the device performs as claimed.
The Subject Devices' comparison with the Predicate Device establishes that they have similar functionality, intended use and technological characteristics. Therefore, we believe that the Subject Device can be considered substantially equivalent to the predicate device.