Brainlab AG
% Chiara Cunico
Manager Regulatory Affairs
Olof-Palme-Str. 9
Munich, Bavaria 81829
GERMANY

April 9, 2021

Re: K203681
Trade/Device Name: RT Elements, Cranial SRS w/ Cones, Multiple Brain Mets SRS, Cranial SRS, Spine SRS, RT QA, Dose Review
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: Class II
Product Code: MUJ
Dated: March 15, 2021
Received: March 18, 2021

Dear Chiara Cunico:

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,

Michael D. O'Hara For

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K203681

Device Name
RT Elements ,Cranial SRS w/ Cones, Multiple Brain Mets SRS, Cranial SRS, Spine SRS, RT QA, Dose Review

Indications for Use *(Describe)*
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 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 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 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.

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.

K203681

510(k) Summary

March 15, 2021

General Information	
Manufacturer	Brainlab AG; Olof-Palme Str.9, 81829, Munich, Germany
Establishment Registration	8043933
Device Name	System, planning, radiation therapy treatment
Trade Name	RT Elements, Cranial SRS w/ Cones, Multiple Brain Mets SRS, Cranial SRS, Spine SRS, RT QA, Dose Review
Classification Name	Medical charged-particle radiation therapy system
Product Code	MUJ
Regulation Number	892.5050
Regulatory Class	II
Panel	Radiology
Predicate Device(s)	iPlan RT K103246

Contact Information	
Primary Contact	**Alternate Contact**
Chiara Cunico Manager RA Phone: +49 89 99 15 68 0 Email: chiara.cunico@brainlab.com	Regulatory Affairs Brainlab Phone: +49 89 99 15 68 0 Fax: +49 89 99 15 68 5033 Email: regulatory.affairs@brainlab.com

1. Intended 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 **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 **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 **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.

In addition to the more generic indications for use, as also present in the predicate device, the RT Elements also include specific indications for each element. Cranial SRS w /Cones is the newest addition to the RT Elements group and the main focus within this submission. Since the functionality of Cranial SRS w /Cones is based on the same Circular Cone Algorithm as in the predicate device and now there is more information provided in label, the change in wording does not affect the safety and effectiveness of the device.

2. Device Description

The RT Elements group consist of different applications, referred to as Elements, intended for radiation treatment planning for use in stereotactic, conformal, computer planned, Linac based radiation treatment of cranial, head and neck, and extracranial lesions.

The newest addition to the RT Elements group is the Cranial SRS w/ Cones element, which is a software application used for automatic radiation treatment planning for either functional areas (e.g. trigeminal neuralgia) or cranial lesions using conical collimators.

Cranial SRS w/Cones 3.0
UDI-DI: 04056481000530
Cranial SRS w/ Cones has no variants.

The device can be used in a hospital environment, in a clinical planning office by medical professionals who perform radiation treatment planning (medical physicists, radiation oncologists, dosimetrists, physicians, etc.).

Cranial SRS w/ Cones offers features for plan calculation (selection of machine profile and clinical protocols, dose calculation, etc.), plan review (isodose lines, Conformity index/gradient index, min and max doses review, etc.), as well as, saving and exporting plan options. It is a software only device, with no patient contact.

For the dose calculation optimization, the Circular Cone dose algorithm is used which is based on different publications:

- Rice, R. K., Hansen, J. L., Svensson, G. K., Siddon, R. L.; Measurements of dose distributions in small 6MV x-rays. Phys. Med. Biol. 32; 1987; 1087-1099
- Luxton G, Jozsef G, Astrahan M A; Algorithm for dosimetry of multiarc linear-accelerator stereotactic radiosurgery. (1991) Med. Phys. 18 pp 1211 - 1221.
- Hartmann G. H. (Editor) Quality Assurance Program on Stereotactic Radiosurgery: Report from a Quality Assurance Task Group. (1995) Published by Springer-Verlag, Berlin Heidelberg.

In general, the main assumption of stereotactic dose calculation models, like the circular cone dose calculation algorithm, is that secondary scatter can be assumed to be of limited significance. Several authors have proposed and investigated this hypothesis (Rice et al 1987, Luxton et al 1991, Hartmann et al 1995) and dose calculations have tended to be a function of only three basic beam parameters: tissue phantom ratios, relative output factors and single beam profiles. Scatter (in particular phantom scatter) is considered to be implicit to these measurements and does not vary significantly with depth in a medium.

The accuracy (reproducibility of measured beam data) of the circular cone dose algorithm is within 1%/1mm.

The circular cone dose calculation algorithm has limited accuracy for dose calculations near inhomogeneous areas such as lung or bone tissue or close to the tissue border (both within a range of a few centimeters). When using the circular cone dose calculation algorithm in dose calculations for depths different from the depth at which the off-axis ratios have been measured, the results may be inaccurate. The calculated penumbra width may be different from the penumbra in the real dose delivered.

3. Substantial Equivalence

Conical Collimator Planning is the technological principle for both the subject and predicate devices. It is based on the circular cone dose calculation algorithm which is basically identical in both devices.

At a high level, the subject and predicate devices are based on the following same technological elements:

- Radiation treatment planning software
- Circular Cone dose calculation algorithm
- Radiation modality (=photons)
- Support of conical collimators
- Similar GUI layouts (e.g. arc plane view layout)

The following technological differences exist between the subject and predicate devices:

- New GUI Design

However, these differences do not raise any questions of safety or efficacy since these functionalities have been successfully tested for their efficacy.

There is also a change in wording on the indications for use, which now provides more information, with no impact on the use of the device.

4. Performance Data

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of

Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "major" level of concern.

The verification of the subject device has been carried out thoroughly both at the top-level including compatibility testing and on the underlying modules. The verification was done according to verification plan to demonstrate that the design specifications are met. The validation was done according to clinical evaluation plan and included usability testing as well as dose measurements. All test reports were finally rated as successful according to their acceptance criteria. The non-clinical validation has been performed with software and units that are considered equivalent to the final version of the product, as warranted by 21 CFR 820.30 (g) and which have the UI as planned for the release.

No clinical tests have been included in this pre-market submission.

5. Conclusion

The comparison of the Cranial SRS w/ Cones (subject device) with the predicate device(s) iPlan RT shows that the subject device has similar functionality, intended use, technological characteristics, and typical users as the predicate device(s). Verification and validation activities ensured that the design specifications are met and that the subject device does not introduce new issues concerning safety and effectiveness. Hence, Brainlab believes that the subject device is substantially equivalent to the predicate device.