DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Brainlab AG
% Mr. Alexander Schwiersch
Regulatory Affairs Manager
Olof-Palme-Str.9
Munchen, 81829
GERMANY

August 24, 2017

Re: K170750
Trade/Device Name: RT Elements, Cranial SRS, Spine SRS, Multiple Brain Mets SRS, RT QA, Adaptive Hybrid Surgery Analysis, Dose Review
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: MUJ
Dated: August 2, 2017
Received: August 7, 2017

Dear Mr. Schwiersch:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

For

Robert Ochs, 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K170750

Device Name
RT Elements, Cranial SRS, Spine SRS, Multiple Brain Mets SRS, RT QA, Adaptive Hybrid Surgery Analysis, 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 "Dose Review" application as one RT Element contains features for review of isodose lines, review of DVHs, dose comparison and dose summation.

The "Multiple Brain Mets SRS" application as one RT Element provides optimized planning and display for cranial multi-metastases radiation treatment planning.

The "Adaptive Hybrid Surgery Analysis" application as one RT Element simulates an automated template-based radiation treatment plan. The simulated plan is intended for treatment evaluation for example in tumor board meetings or operating rooms.

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.

"RT QA" is an accessory to the RT Elements and 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.

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 FOR RT ELEMENTS

Manufacturer:	Brainlab AG Olof-Palme-Str. 9 81829 München Germany Phone: +49 89 99 15 68 0 Fax: +49 89 99 15 68 5033
Submitter:	Rainer Birkenbach
Contact person:	Alexander Schwiersch
Summary date:	7/7/2017
Device:	RT Elements
Trade name:	Dose Review, Multiple Brain Mets SRS, Cranial SRS, Spine SRS, RT QA
Common/Classification Name:	System, Planning, Radiation Therapy Treatment
Primary predicate Device:	K170355 Raystation 6
Reference Devices:	K142108 RT Elements K103246 iPlan RT
Device classification name:	Medical charged-particle radiation therapy system
Regulatory Class:	Class II
Regulation Number:	21 CFR 892.5050
Product Code:	MUJ
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.
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 **Dose Review** application as one RT Element contains features for review of isodose lines, review of DVHs, dose comparison and dose summation.

The **Multiple Brain Mets SRS** application as one RT Element provides optimized planning and display for cranial multi-metastases radiation treatment planning.

The **Adaptive Hybrid Surgery Analysis** application as one RT Element simulates an automated template-based radiation treatment plan. The simulated plan is intended for treatment evaluation for example in tumor board meetings or operating rooms.

Content of this submission:
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.

RT QA is an accessory to the RT Elements and 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.

Device description:

The **Dose Review** application as one RT Element contains features for review of isodose lines, review of DVHs, dose comparison and dose summation.

The **Multiple Brain Mets SRS** application as one RT Element provides optimized planning and display for cranial multi-metastases radiation treatment planning.

The **Adaptive Hybrid Surgery Analysis** application as one RT Element simulates an automated template-based radiation treatment plan. The simulated plan is intended for treatment evaluation for example in tumor board meetings or operating rooms.

The **Cranial SRS** application as one RT Element provides optimized planning and display for radiation treatment planning for single lesions in the cranium. Cranial SRS 1.0 provides single lesion planning using a Volumetric Modulated Arc Therapy (VMAT) optimization, thus allowing dose modulation with both the MLC leaf positions and the dose rate or gantry speed. It particularly offers planning for lesions in the brain which benefit from dose modulation like large tumors close to organs at risk with a complex geometry. These indications include, but are not limited to Vestibular Schwannomas, Pituitary Adenomas, Meningiomas and Gliomas. Cranial SRS 1.0 can also be used for treating vascular anomalies like arteriovenous malformations (AVMs).

The **Spine SRS** application as one RT Element provides optimized planning and display for single spine metastases.

RT QA is an accessory to the RT Elements and 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.

Operator Profile:
Typical users of the RT Elements are medical professionals who perform radiation treatment planning (medical physicists, radiation oncologists, dosimetrists, physicians, etc.).

Patient Population:
There are no demographic, regional or cultural limitations for patients. It is up to the user to decide if the system shall be used to assist a certain procedure

Conditions of use:
The system can be used in a hospital environment, in a clinical planning office.

Dose Calculation algorithms:
The Brainlab pencil beam dose algorithm is based on publications by Mohan et al (1985, 1986, and 1987).

- Mohan R, Chui C, Lidofsky L; Energy and angular distributions of photons from medical accelerators. (1985) Med. Phys. 12 pp 592 - 597.
- Mohan R, Chui C, Lidofsky L; Differential pencil beam dose computation model for phot (1986) Med. Phys. 13 pp 64 - 73.
- Mohan R, Chui C; Use of fast fourier transforms in calculating dose distributions for irre shaped fields for three-dimensional treatment planning. (1987) Med. Phys. 14 pp 70 - 7

The Brainlab Monte Carlo algorithm is based on the X-ray Voxel Monte Carlo algorithm developed by Iwan Kawrakow and Matthias Fippel (Kawrakow et al 1996, Fippel et al 1997, Fippel 1999, Fippel et al 1999, Kawrakow and Fippel 2000, Fippel et al 2003, Fippel 2004).

- Fippel M: Fast Monte Carlo dose calculation for photon beams based on the VMC algorithm, Medical Physics 26 (1999) 1466-1475.
- Fippel M: Efficient particle transport simulation through beam modulating devices Carlo treatment planning, Medical Physics 31 (2004) 1235-1242.
- Fippel M, Haryanto F, Dohm O, Nüsslin F, Kriesen S: A virtual photon energy fluer Monte Carlo dose calculation, Medical Physics 30 (2003) 301-311.
- Fippel M, Kawrakow I, Friedrich K: Electron beam dose calculations with the VMC and the verification data of the NCI working group, Physics in Medicine and Biolo 501-520.
- Fippel M, Laub W, Huber B, Nüsslin F: Experimental investigation of a fast Monte beam dose calculation algorithm, Physics in Medicine and Biology 44 (1999) 303

- Kawrakow I, Fippel M: Investigation of variance reduction techniques for Monte dose calculation using XVMC, Physics in Medicine and Biology 45 (2000) 2163
- Kawrakow I, Fippel M, Friedrich K: 3D Electron Dose Calculation using a Voxel Carlo Algorithm (VMC), Medical Physics 23 (1996) 445-457.

The accuracy of both algorithms is tested according to IAEA-TECDOC-1540 to be better than 3%.

The pencil beam 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). The Monte Carlo algorithm is affected by the general limitation that in some cases the Hounsfield-Unit values of the CT scan do not represent the real characteristics of a material (e.g. mass density and material composition). This may lead to inaccurate dose calculation for non-human tissue materials (e.g. implants).

Substantial equivalence:

The RT Elements are the current RT planning software generation of Brainlab. New in the RT Elements are the following features:

- Treatment planning using the VMAT optimization algorithm and
- Optimized arc placement

VMAT algorithm for dose planning:

Following the decision making flowchart in appendix A of the guideline *Evaluating Substantial Equivalence in Premarket Notifications [510(k)]* we evaluated the substantial equivalence in respect to the new feature VMAT algorithm for dose planning between the primary predicate Raystation 6 (K170355). And the subject device of this submission. The primary predicate is legally marketed and the devices have the same intended use. The following table compares the technological characteristics of the two devices in respect of the VMAT algorithm for dose planning:

Technological characteristics	**Raystation 6 (K170355)**	**RT Elements (K170750)**
Optimization based on constraints for organs at risk	Yes	Yes
Direct optimization of MLC leaf positions	Yes	Yes
Direct optimization of dose rate	Yes	Yes
Direct optimization of gantry speed	Yes	Yes
Possibility to create single or multiple-arc plans	Yes	Yes
Possibility to use constant dose rate	Yes	Yes
Fulfillment of all accelerator constraints	Yes	Yes

Final forward dose calculation for the optimization result	Yes	Yes
Export of the optimized treatment plan via DICOM RT	Yes	Yes

Optimized arc placement

The primary predicate Raystation 6 (K170355) offers the 3D-CRT optimization module, which is in all relevant parts comparable to the optimized arc placement included in RT Elements. The Raystation 3D-CRT optimization module offers a wide variety of optimization possibilities, while the optimization offered in the RT Elements is restricted to table angle optimization and gantry start and stop angle optimization.

Following the decision making flowchart in appendix A of the guideline *Evaluating Substantial Equivalence in Premarket Notifications [510(k)]* we evaluated the substantial equivalence in respect of the new feature optimized arc placement between the second predicate device Raystation 6 (K170355) and the subject device of this submission RT Elements (K170750). The predicate device K170355 is legally marketed (decision 1) and the devices have the same intended use (decision 2) The following table compares the technological characteristics of the two devices in respect of the optimized arc placement:

Technological characteristics	**Raystation 6 (K170355)**	**RT Elements (K170750)**
Optimization based on organs at risk	Yes	Yes
Optimization of table angles	Yes	Yes
Optimization of gantry angles	Yes	Yes
Final forward dose calculation for the optimization result	Yes	Yes
Export of the optimized treatment plan via DICOM RT	Yes	Yes

Conclusion: According to these tables all technological characteristics in respect of the VMAT algorithm for dose planning and optimized arc placement of the predicate device and the RT Elements are the same. Therefore these features are substantially equivalent.

Technological Characteristics of subject device compared to reference devices:

	device features of reference device iPlan RT (K103246)	device features of reference device RT Elements (K142108)	Device features of subject device
Characteristics			
DICOM Viewing	Yes	Yes	Yes
Photon beam planning	Yes	Yes	Yes
3rd party Hardware support	Yes	Yes	Yes
User interface control with touchscreen and mouse/keyboard	Yes	Yes	Yes
DICOM Image import	Yes	Yes	Yes
DICOM Segmentation import	Yes	Yes	Yes
DICOM RT Registration import	Yes	Yes	Yes
DICOM RT Export	Yes	Yes	Yes
Loading and Saving	Yes	No	Yes
3D Viewing	Yes	Yes	Yes
Treatment workflow support	Yes	Yes	Yes
Dose Calculation with Pencil Beam	Yes	Yes	Yes
Dose Calculation with Monte Carlo	Yes	No	Yes
Quality Assurance possibilities	Yes	No	Yes
User defined treatment templates	Yes	Yes	Yes

Verification/validation summary:

Verification:
The verification of the existing and new features of the RT Elements has been carried out throughout both at the top level and on the underlying subsystem. Planning through VMAT as well as quality assurance and saving and loading of treatment plans was successfully verified. The verification was done according to verification plans to demonstrate that the design specifications are met.

Validation:
The validation was done according to the validation plans containing usability tests which ensure that workflows or user interface are suitable for radiotherapy treatment planning. Furthermore clinical experts evaluated the clinical suitability of radiation therapy planning using the Cranial SRS and Spine SRS workflows. The acceptance and deliverability of VMAT treatment plans was successfully validated.

All tests reports were rated as successful according to the acceptance criteria. The validation was performed with software versions 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.