SPECIAL 510 (K) SUMMARY RT ELEMENTS

K190664

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Summary date:	2/26/2019
Device:	RT Elements
Trade name:	Dose Review, Multiple Brain Mets SRS, Cranial SRS, Spine SRS, RT QA, Adaptive Hybrid Surgery Analysis
Common/Classification Name:	System, Planning, Radiation Therapy Treatment
Primary predicate Device:	K170750 RT Elements 1.3
Device classification name:	Medical charged-particle radiation therapy system
Regulatory Class:	Class II
Regulation Number:	21 CFR 892.5050
Product Code:	MUJ
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.

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 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. There are several applications defined as an RT Element.
The RT Elements are released as a system. Each RT Element is released as a separate subsystem including risk analysis, verification and usability as well as design input an review activities. The system can be seen as container and documents compatibility between the elements. In addition, validation activities of the RT Elements are documented in the system as well as service and user documents.

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 flue 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).

Reason for the Special 510(k) submission:	The RT Elements are cleared with K170750 The 510(k) for the new RT Elements generation is triggered by the new optimization algorithm implemented in Multiple Brain Mets SRS 2.0. The algorithm was rewritten in order to increase robustness and consider additional objectives. It was successfully verified and validated that optimization results of the new algorithm is equivalent to the algorithm used in the predicate device. Changes to the remaining RT Elements have been investigated and found to be uncritical and equivalent to the predicate device. The intended use did not change.
Substantial equivalence:	The RT Elements have been verified and validated according to Brainlab procedures for product design and development. The information provided by Brainlab in this Special 510(k) application supports the claim of substantial equivalence to the predicate device.

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. 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 planning 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 RT Elements workflows. 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.