DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
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See PRA Statement below.

510(k) Number *(if known)*

K190664

Device Name
RT Elements

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

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.

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.

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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