DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

Brainlab AG
% Mr. Alexander Schwiersch
Regulatory Affairs Manager
Kapellenstrasse 12
85622 Feldkirchen
GERMANY

December 16, 2014

Re: K142108
Trade/Device Name: RT Elements
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: MUJ
Dated: November 17, 2014
Received: November 21, 2014

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 yours,

Robert A. Ochs, Ph.D.
Acting 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)*

K142108

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

The "Brain Metastases" 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.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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510 (K) SUMMARY
RT ELEMENTS

IN ACCORDANCE WITH REQUIREMENTS OF 21 CFR PART 807.92

Manufacturer:	Brainlab AG Kapellenstrasse 12 85622 Feldkirchen Germany Phone: +49 89 99 15 68 0 Fax: +49 89 99 15 68 33
Submitter:	Rainer Birkenbach
Contact person:	Alexander Schwiersch
Summary date:	12/5/2014
Device:	RT Elements
Trade name:	Elements Dose Review, Elements Brain Metastases, Elements Adaptive Hybrid Surgery Analysis
Common/Classification Name:	System,Planning,Radiation Therapy Treatment
Main Predicate Device:	iPlan RT (K103246)
Secondary Predicate Device:	Not applicable
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 “Brain Metastases” 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.

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 “Brain Metastases” 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.

Operator Profile
Typical users are medical professionals, including but not limited to radiation oncologists, medical physicists or physicians as well as neurosurgeons (for Adaptive Hybrid Surgery Analysis)

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 doctor’s office, at the operating theater in case of Adaptive Hybrid Surgery Analysis

Substantial equivalence:

The RT Elements are part of a new software generation at Brainlab. The features provided by the RT Elements including viewing of DICOM RT data, radiation treatment planning for stereotactic radiotherapy treatments is not a new technology for Brainlab. The intended use is considered substantially equivalent to what is possible with iPlan RT as predicate device. The single Elements to not provide the complete features of the predicate device but allow a subset of functionality of the predicate device.

Conclusion:

The RT Elements and iPlan RT have identical functionalities in DICOM viewing and identical technical characteristic. The RT functionalities are equivalent to those of iPlan RT.

Verification/validation summary:

Verification

The verification of the RT Elements has been carried out thoroughly both at the top level and on the underlying subsystems. The verification was done according to verification plan to demonstrate that the design specifications are met.

Non-clinical validation

The validation was done in accordance with the validation plan containing usability tests which should ensure that workflows or user interface result in a useful interface.

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.