



October 1, 2019

SegAna, LLC
% Ms. Jennifer Bosley
Principal Consultant
Jennifer Bosley Consulting
10336 Wittenberg Way
ORLANDO, FL, 32832

Re: K191610
Trade/Device Name: RTapp™ v1.0
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system.
Regulatory Class: Class II
Product Code: LLZ
Dated: July 2, 2019
Received: July 3, 2019

Dear Jennifer Bosley:

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,

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

Indications for Use

510(k) Number (if known)

K191610

Device Name

RTapp™ v1.0

Indications for Use (Describe)

RTapp™ is a stand-alone software that provides a means for comparison of imaging data that is DICOM compliant. It allows the registration and display of medical images as an aid during use by radiation oncology.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

I. SUBMITTER

SegAna LLC
3259 Progress Drive
Orlando, FL 32826 USA

SegAna Phone: (484) 291-1087
Contact Person: Rodney Bosley, President & CEO
Date Prepared: July 2, 2019

II. DEVICE

510(k) Number: K191610
Name of Device: *RTapp*™ v1.0
Common or Usual Name: Image Processing Aid to Radiation Therapy Treatment Planning
Classification Name: Picture archiving and communications systems
Regulation Number: 21 CFR §892.2050
Regulatory Class: II
Product Code: LLZ – System, Image Processing, Radiological

III. PREDICATE DEVICE

Velocity™ 4.0 (K173636, Varian Medical)
This predicate was not subject to a design-related recall.
No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

RTapp v1.0 is a stand-alone, cloud-based software medical device with secure access via a private internet web portal. *RTapp* analyzes and visualizes the day-to-day variations in a radiation therapy patient's individual anatomical structures and the effect of those changes on the treatment dose; an aid during use by radiation oncology.

The *RTapp* software:

- Automatically queries and retrieves treatment plan data and images from any DICOM compliant equipment.
- Automatically processes all patient's treatment fractions, flagging and presenting an advance warning of treatment plans at risk with an email notification.
- Monitors and evaluates treatment plan performance in real time by using the Plan Performance Dose Volume Histogram (DVH). The DVH projects the amount of dose to be delivered.

- Displays Deformable Image Registration contours, cross correlation metrics and flagging of large deformations.
- Projects when Organs At Risk will exceed dose constraints.
- Dose estimation
- Generates reports as PDF with images and graphs.

RTapp is intended for use by radiation oncology professionals in a hospital/clinical setting for any patient undergoing radiation therapy based on a treatment plan.

RTapp is NOT intended as a treatment planning software and cannot be used to generate radiotherapy treatment plans.

V. INDICATIONS FOR USE

RTapp is a stand-alone software that provides a means for comparison of imaging data that is DICOM compliant. It allows the registration and display of medical images as an aid during use by radiation oncology.

Differences in Indications For Use:

The Indications For Use for *RTapp* are not identical to the predicate device; however, the indications for use of the *RTapp* falls within the intended use of the predicate device and, therefore, the two devices have the same intended use. The differences do not alter the intended use of the device nor does it affect the safety and effectiveness of the device relative to the predicate. Both the subject and predicate devices have the same intended use: comparison of DICOM-compliant imaging data as an aid in radiation oncology.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Comparison of DICOM-compliant imaging data as an aid in radiation oncology is the technological principle for both the subject and predicate devices.

The subject and predicate devices are based on the following same technological elements:

- Software devices
- Imports and compares imaging data with CT images through DICOM

The following differences exist between the subject and predicate device:

- Predicate imports DICOM, PET/SPECT/CT/MRI images. Subject device imports DICOM, CT images only.
- Predicate can be used with diagnostic radiology, oncology, radiation therapy planning and other medical specialties. Subject device used with radiation oncology.
- Predicate is used to aid in creating treatment plans. Subject device is used to review daily treatment dose and compare it to established treatment plan dose.

VII. PERFORMANCE DATA

Performance data was provided in support of the substantial equivalence determination.

Software Verification and Validation Testing

Software verification and validation testing was 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."

Although the *RTapp* software was considered a "major" level of concern by the FDA, a failure or latent flaw in the software will not directly result in serious injury or death to the patient or user. The major level of concern was determined because the software was considered related to RT treatment planning and QA.

VIII. CONCLUSIONS

Non-clinical data support the safety and efficacy of the device. The software verification and validation demonstrate that the *RTapp* device should perform as intended in the specified use conditions.