November 10, 2021

SegAna, Inc.
℅ Ms. Jennifer Bosley,
Sr. Director of Quality & Regulatory Affairs
3259 Progress Drive
ORLANDO FL 32826

Re: K212887
Trade/Device Name: RTapp™ v2.0
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: LLZ
Dated: September 8, 2021
Received: September 10, 2021

Dear Ms. 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 and Part 809); 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,

for
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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212887

Device Name

RTapp™ v2.0

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

I. SUBMITTER

SegAna, Inc.
3259 Progress Drive
Orlando, FL 32826 USA

Telephone: 866-347-0898
Contact Person: Jennifer Bosley, MBA, RAC
Date Prepared: November 9, 2021

II. DEVICE

510(k) Number:	K212887
Name of Device:	*RT*app™ v2.0
Common/Usual Name:	Image Processing Aid to Radiation Therapy Treatment Planning
Classification Name:	Medical Image Management and Processing System
Regulation Number:	21 CFR §892.2050
Regulatory Class:	II
Product Code:	LLZ – System, Image Processing, Radiological

III. PREDICATE DEVICE

*RT*app™ v1.0 (K191610, SegAna, Inc.)
This predicate has not been subject to a design-related recall.

No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

*RT*app™ v2.0 is a stand-alone software medical device. *RT*app 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; it is an aid during use by radiation oncology.

The *RT*app 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.

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

The Indications For Use statement for *RT*app™ v2.0 is identical to the predicate device. Both the subject and predicate devices have the same intended use and indications for use.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The technological characteristics of the subject device and the predicate device are the same, Deformable Image Registration using an "Optical-Flow" algorithm for the comparison of DICOM-compliant imaging data as an aid in radiation oncology. The following difference exists between the subject and predicate device:

- Predicate device only imports data for comparison, while the subject device can import and export data.

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, *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*. The *RT*app software is considered a "Major" level of concern.

Non-clinical, verification and validation (V&V) performance testing was conducted on anonymized, retrospective, clinically-relevant data using computer systems for single and multi-users that met minimum configuration specifications in order to test the device design requirements and user needs. *RT*app™ v2.0, which includes some off-the-shelf software, underwent V&V testing and regression analysis of manual test

suites interfacing with external DICOM servers. The following features for comparing DICOM-compliant images were tested: automated and manual workflows, image visualization, alignment, settings for configuring the dashboard and visual displays, user interface, importing and exporting DICOM data, processing and loading time, dose volume histogram graphs, and reports. All test protocols passed, and acceptance criteria were met indicating successful verification and validation of the subject device and substantial equivalence to the predicate device.

VIII. CONCLUSION

Non-clinical performance data show the *RT*app™ v2.0 is substantially equivalent to the predicate device. The software verification and validation demonstrate that the *RT*app™ v2.0 device should perform as intended in the specified use conditions.