# 510(k) Summary

**Date Summary Prepared:** May 4, 2011

**Trade Name:** Segasist Prostate Auto-Contouring Software

**Common Name:** Segasist P-AC/Medical Image Processing Software

**Classification:** Class II device

**Classification Name:** System, Image Processing, Radiological

**CFR Classification:** 21 CFR 892.2050

**Product Code :** LLZ

**Manufacturer:** Segasist Technologies
MaRS Centre, South Tower,
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**Legally Marketed Predicate Devices:**

The Segasist P-AC contouring software utilizes the same technological characteristics, has the same intended use and, is substantially equivalent to at least four predicate devices previously cleared for commercial distribution. The enclosed information for four of these predicates demonstrates substantial equivalence. These commercial products include:

1. **Medviso AB's** Segment software cleared for market via K090833
   **Trade Name:** Segment / Image Processing System
   **Product Code:** LLZ
   **Classification:** 21 CFR 892.2050
   **Class:** II
2. **Computerized Medical Systems, Inc.'s** Atlas-Based Autosegmentation Software, cleared for market via K080799
   **Trade Name:** Atlas-Based Autosegmentation
   **Product Code:** LHN and MUJ
   **Classification:** 21 CFR 892.5050
   **Class:** II
3. **IKOEtech, LLC's** IKOEngelo™ software cleared for market via K083591
   **Trade Name:** IKOEngelo™
   **Product Code:** KPQ
   **Classification:** 21 CFR 892.5840
   **Class:** II
4. **Siemens AG**, Contouring Software Package, cleared for market via K071310
   **Trade Name:** *syngo* CT Oncology
   **Product Code:** JAK

**Classification:** 21 CFR 892.1750
**Class:** II

In each of these software devices, including the Segasist P-AC software, the analysis software is used to receive images from various sources, which can then be stored, communicated, manipulated, annotated, measured, compared and displayed at workstations with the appropriate configurations.

Detailed information regarding each of these predicates, including their 510(k) Summaries and Indications for Use can be found in Section 23 – Other: Predicates, of this Traditional Premarket Notification 510(k) submission for ease of reference.

**Device Description:**

Segasist P-AC (**Seg**mentation **Assist**ant for **P**rostate – **A**uto-**C**ontouring) is a standalone atlas-based segmentation software tool for auto-contouring of the prostate gland from different input image modalities (Computed Tomography (CT) scans, Magnetic Resonance (MR) images, ultrasound scans). The software can read, write and display DICOM images from/to local directories, and offers the possibility of defining regions of interest (ROIs) around the prostate gland in order to delineate the prostate for contouring, visual assessment, and size and volume calculation purposes, either manually, or via semi-automated or automated processes.

The Segasist P-AC software is a tool that has been designed and developed to assist clinicians (radiologists, oncologists, medical physicists etc.) in performing contouring/delineation of the prostate gland in images in multiple modalities more efficiently. The software is capable of segmenting the prostate gland in individual slices, in a choice of different modalities, and for any given view (axial, sagittal, or coronal). This is done by requiring some user input (clicks or drawing ROIs).

For volume prostate data, Segasist P-AC calculates the prostate volume in cubic centimeters and displays the contours on each slice. The results (contours) can be saved as DICOM or binary images (BMP), which can be edited/modified at any time, completely dismissed or accepted and saved by the end user.

The efficiency of contouring performed by the Segasist P-AC software may be improved by generating/using an advanced atlas using gold standard images created by the experienced clinician(s). This requires the software to be trained (atlas creation) before being used. The software can be delivered pre-trained with the comprehensive atlas or the end user can generate their own atlas; a well-established practice for atlas-based segmentation software products.

Segasist P-AC also offers a built-in editor, enabling the user to edit, modify, or change the extracted prostate boundaries to their desired configuration based on their medical and clinical knowledge and experience. The results provided by the Segasist P-AC software needs to be approved by the experienced clinician and can always be modified or corrected by him/her. In addition, the end user can delineate the prostate gland manually using the P-AC software, if necessary or desired. As a result, when Segasist P-AC generates a result, the expert user always has the final decision to override the software result, if deemed appropriate in his/her clinical judgment. It is up to the expert user to accept the result without any change, reject it completely and delineate manually, or modify the Segasist P-AC result and then save it. The software does not provide any auto-detection or auto-saving functionalities. Regardless of the accuracy of Segasist P-AC result, it is always the experienced clinician that remains the decision maker regarding the acceptability of the computed segmentation. Therefore, the final decision

on diagnosis, treatment and overall management of the patient is not based on the software result.

Segasist P-AC software does not alter the original input images of the prostate gland, nor does it change the final results obtained once approved by the clinical expert.

Segasist P-AC offers several features and functionalities such as, but not limited to:

- Import/Export DICOM images
- Saving Contours to DICOM or BMB format
- Semi-automated Segmentation
- Auto-Segmentation (fast slice-to-slice auto-segmentation with minimal user interactions)
- Volume Segmentation and measurement
- Edge Enhancement (contour enhancement by user controlled edge snapping).
- Standard Functionalities for Image Visualization (windowing, contrast, brightness, zoom, panning etc)
- Advanced Functionalities for Contour Editing For Manual Segmentation (drawing, inflating, deflating, shifting, cut & add etc)
- User access to modify the resulting contours at any time

**Proposed Intended Use / Indications for Use:**

Segasist P-AC contouring software is a standalone software application for Windows platforms that assists clinicians in generating estimates of the anatomy boundary contours of the prostate gland in Computed Tomography (CT) scans, Magnetic Resonance (MR) images and ultrasound (sonography) scans to aid in patient diagnosis, treatment-planning and post-treatment monitoring. The software is intended to be used to provide clinicians with tools to efficiently contour/delineate the prostate gland in volume data and save the results in DICOM and BMP format. The clinician has the ability to use the saved contours directly or import them in other software tools to perform the task at hand.

The clinician retains the ultimate responsibility for making the pertinent diagnosis and patient management decisions based on their standard practices and visual comparison of the individual images. The Segasist P-AC software tool is a compliment to manual contouring techniques.

**Testing:**

The Segasist P-AC software was designed and developed with the input and collaboration of experienced and trained professionals, such as radiologists, oncologists or other highly qualified medical clinicians that are proficient in reading, evaluating and interpreting images of the prostate produced by MR, CT or ultrasound devices. The input was captured in a written and approved Software Requirement Specifications Document. The Segasist P-AC software has been developed in a manner consistent with accepted standards for software development, including both unit and system integration testing. Testing was conducted both internally at Segasist Technologies and independently by experienced and trained medical professionals who are representative of the commercial end users of the software using clinical test cases. No clinical testing was conducted to demonstrate safety or effectiveness as device bench testing was completed using imported images from the various imaging modalities of the prostate in sufficient numbers to support the intended use of the device. This bench testing deemed that the

Segasist P-AC software works as intended, was acceptable for clinical use, and did not introduce any new concerns of safety or effectiveness compared to predicate products or manual contouring of the prostate gland.

As noted, imported prostate image datasets from the various imaging modalities were used as input for testing of the software functionalities in accordance with the software validation/verification plans. A full description of the software functionality, device hazard analysis, software requirements, and verification and validation testing can be found in Section 18 – Software, of this submission.

The device has no patient contacting materials and is utilized only by trained professionals. The output of the device is evaluated by professionals skilled in reading, evaluating and interpreting images of the prostate gland produced by CT, MR or ultrasound, which allows sufficient review for identification and intervention in the event of a malfunction. Device output and analysis is not real-time with respect to patient involvement or presence, and is only used to aid the end user in the further evaluation of the available prostate imaging data. Additional clinically relevant parameters / tests, including data from alternative imaging modalities, must be used in addition to the output of the Segasist P-AC software, in the diagnosis, treatment planning and on-going management of the patient. The device does not impact the quality or status of the original acquired imaging data.

**Conclusions:**

The Segasist P-AC contouring software has the same intended use and similar technological characteristics as the previously noted predicate software devices. As demonstrated within this Traditional Premarket Notification, there are no substantial differences between the Segasist P-AC contouring software and the stated predicate devices, and therefore, the Segasist P-AC software does not introduce any new concerns related to safety or effectiveness. The data contained within this Premarket Notification 510(k) submission is sufficient to deem the Segasist P-AC software substantially equivalent to those predicates described within this application.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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CANADA

OCT 17 2011

Re: K111311
Trade/Device Name: Segasist Prostate Auto-Contouring (Segasist P-AC) Software
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: MUJ, LLZ
Dated: September 6, 2011
Received: September 7, 2011

Dear Ms. Manners:

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.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. 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 Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

# Indications for Use

**510(k) Number (if known):** K111311

**Device Name:** Segasist Prostate Auto-Contouring (Segasist P-AC) Software

**Indications for Use:**

Segasist P-AC contouring software is a standalone software application for Windows platforms that assists clinicians in generating estimates of the anatomy boundary contours of the prostate gland in Computed Tomography (CT) scans, Magnetic Resonance (MR) images and ultrasound (sonography) scans to aid in patient diagnosis, treatment planning and post-treatment monitoring. The software is intended to be used to provide clinicians with tools to efficiently contour/delineate the prostate gland in volume data and save the results in DICOM and BMP format. The clinician has the ability to use the saved contours directly or import them in other software tools to perform the task at hand.

The clinician retains the ultimate responsibility for making the pertinent diagnosis and patient management decisions based on their standard practices and visual comparison of the individual images. The Segasist P-AC software tool is a compliment to manual contouring techniques.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Mary S Pastel

(Division Sign-Off)

Division of Radiological Devices

Office of In Vitro Diagnostic Device Evaluation and Safety

510K K111311