Sensus Healthcare, Inc.
Nicolas Soro
QA/RA Manager
851 Broken Sound Parkway NW
Suite 215
Boca Raton, Florida 33487

February 21, 2019

Re: K182665
Trade/Device Name: Sensus TPS Workstation
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical Charged-Particle Radiation Therapy System
Regulatory Class: Class II
Product Code: MUJ
Dated: January 17, 2019
Received: January 22, 2019

Dear Nicolas Soro:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael D. O'Hara For

Robert A. Ochs, Ph.D.
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182665

Device Name
Sensus TPS Workstation

Indications for Use *(Describe)*
Sensus TPS Workstation is a software system intended for treatment planning and analysis of intraoperative radiation therapy administered with the Sensus IORT System, a device suitable for intraoperative radiotherapy.

The treatment plans provide treatment unit set-up parameters and estimates of dose distributions expected during the proposed treatment, and may be used to administer treatments after review and approval by the intended user. The system functionality can be configured based on user needs.

The intended users of Sensus TPS Workstation shall be clinically qualified radiation therapy staff trained in using the system.

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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510(k) Summary

[As Required by 21 CFR 807.92(c)]

Submitter's Name & Address: Sensus Healthcare
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Contact Person: Kal Fishman, COO
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Date Summary Prepared: January 16, 2019

Device Name: Trade/Proprietary Name – Sensus TPS Workstation

Common/Usual Name – Treatment Planning Station

Classification Name – Medically Charged-Particle Radiation Therapy

Predicate Device: Radiance V4 (K171885)

Reference Device: N/A

Device Description:

The Sensus TPS Workstation is a multi-functional, integrated software suite that forms a comprehensive electronic oncology management system for radiation oncology facilities. For radiation oncology users, the TPS Workstation provides image-enabled electronic patient charting and record management. For radiation oncology users, it also includes the ability to import and export radiation treatment plan information, beam geometry planning, treatment plan review, and verification and record treatment setup and delivery. The Sensus Healthcare TPS Workstation is dedicated for use with the Sensus Healthcare IORT System only. The software is not a general-use product compatible with other IORT systems.

Indications for Use:

Sensus TPS Workstation is a software system intended for treatment planning and analysis of intraoperative radiation therapy administered with the Sensus IORT System, a device suitable for intraoperative radiotherapy.

The treatment plans provide treatment unit set-up parameters and estimates of dose distributions expected during the proposed treatment, and may be used to administer treatments after review and approval by the intended user. The system functionality can be configured based on user needs.

The intended user of Sensus TPS Workstation shall be clinically qualified radiation therapy personnel trained in using the system.

Prescriptive Statement

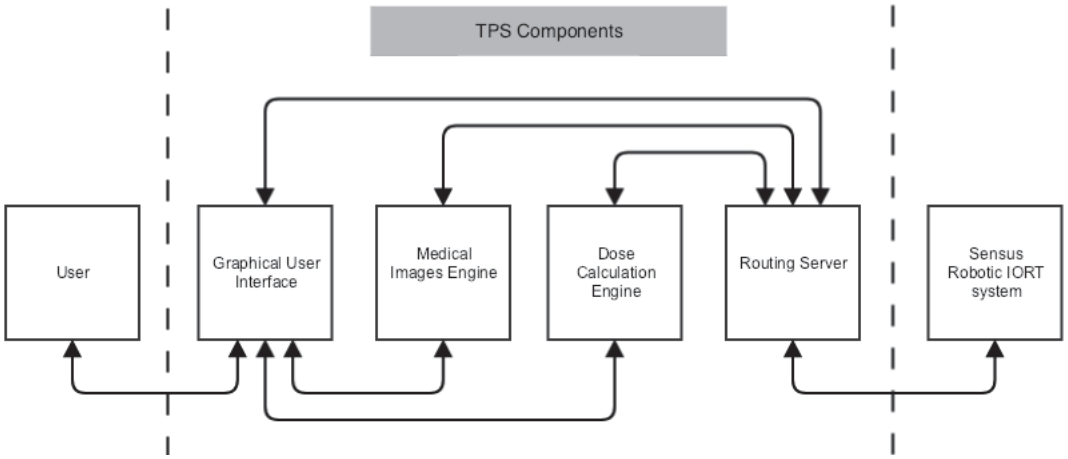
Caution: Federal law restricts this device to sale by or on the order of a physician.

Technological Characteristics/Principles of Operation – System Architecture

From a system architecture standpoint, the basis for the functionality of TPS Workstation is as follows.

Architectural Design

The complete functionality of the TPS Workstation is achieved by partitioning the responsibilities of the system and assigning them to subsystems. The following diagram depicts the subsystems and their inter-relationships.



The following modules are the subsystems associated with the TPS Workstation.

Graphical User Interface

The software that is used to create the GUI is in the form of an iOS application running on an iPad Pro. The responsibilities of this subsystem are:

- Communicate with the routing server to access the DB;
- List the required medical records to do the treatment planning;
- Provide graphical representation of the radiation source target;
- Request medical images from MIE;
- Request dose calculations from DCE;

- Provide multi planar medical viewer for the generated isodose;
- Provide graphical tools for contouring;
- Present 3D reconstruction of selected isosurfaces; and
- Send treatment plan to the IORT system.

Dose Calculation Engine

The software that is used to create the DCE is in the form of daemon running on PC. It was designed to work on both Linux and Windows OS. The responsibilities of this subsystem are:

- Receive requests from the GUI;
- Perform volumetric dose distribution calculations; and
- Provide calculated data to the GUI.

Medical Images Engine

The software that is used to create the MIE is in the form of daemon running on PC. It was designed to work on both Linux and Windows OS. The responsibilities of this subsystem are:

- Receive requests from the GUI;
- Perform interpolation on the medical image; and
- Provide medical image to the GUI.

Routing Server

The software that is used to create the Routing Server is in the form of node.js web service running on a PC. The responsibility of this subsystem is to provide an interface to access the DB of the IORT system.

Non-Clinical Performance Testing:

The Sensus TPS Workstation has undergone thorough design verification and validation testing in accordance with the test protocols listed in Table 1 below. Verification and validation tests were written based on the full system requirements specifications and executed to ensure that the system was functioning in accordance with its design parameters.

The TPS Workstation underwent code Static Analysis and Cyclomatic Complexity, Unit Testing, and System Integration Testing. The software passed all of the requirements determined in the testing procedures.

Performance testing consisted of bench testing that has demonstrated that the performance of the TPS Workstation provided the same technical capabilities as the predicate device. Performance testing was executed to validate the operational characteristics associated with the TPS Workstation as defined in the System Requirements Specification (SRS). The TPS Workstation passed all performance testing, and premised on the test results, supports Sensus Healthcare's claims of system performance and equivalency.

Non-clinical Safety Tests:

The TPS Workstation verification and validation testing included various safety testing to ensure the device fulfilled all of the System Requirements Specifications. These V&V tests included test cases such as: locking down treatment plans to prevent unauthorized/erroneous modifications, approval and disapproval of treatment plans, user authentication and access level control, data integrity and management, and proper communication between the TPS Workstation and the Sensus IORT System.

The TPS Workstation was developed in accordance with IEC 62304 *Medical device software – Software life cycle processes* to ensure proper design and development to all aspects of patient, operator, and device safety. A hazards analysis, risk assessment, and cybersecurity risk assessment were performed to ISO 14971 and FDA Guidance for Management of Cybersecurity in Medical Devices to identify and mitigate any potential causes that may be introduced that lead to a hazard.

The TPS Workstation underwent a comprehensive treatment plan-to-beam generation fidelity testing, which included the generation of several test treatment plans, benchmarking those treatment plans' output yield and results with the DCE's computational engine output and results, and then uploading those test treatment plans to the Sensus IORT System and measuring the actual beam output and yield from the system's x-ray source. The test results gathered proved that the TPS Workstation's performance and treatment plans generation yield accurate and consistent beam output and dose output, which further demonstrates its safety and clinical efficacy.

The TPS Workstation passed all safety testing, and premised on the test results, supports Sensus Healthcare's claims of system safety and efficacy.

Test Standards Employed

Table 1 delineates the testing standards employed by Sensus Healthcare during the design and development of the TPS Workstation.

Table 1 Test Standards & Protocols Employed

Document/Protocol	Name
ISO 62304	Medical device software – Software life cycle processes
ISO 14971	Medical devices -- Application of risk management to medical devices
6-2-7380-0000	TPS Software Verification Validation Test Plan
6-2-7381-0000	TPS Software System Integration Testing
6-2-7390-0000	Static Analysis Report Summary
6-2-7391-0000	Unit Testing Report Summary
SEN18940_RPT	Comparison of the measured dose and the dose calculated by the radiation treatment planning system

Test Results

Table 2 delineates the test results obtained as a result of executing each test protocol.

Table 2 Test Results

Document/Protocol	Date Testing Performed	Results (Pass/Fail)
6-2-7380-0000	1/16/2019	Pass
6-2-7381-0000	1/16/2019	Pass
6-2-7390-0000	1/16/2019	Pass
6-2-7391-0000	1/16/2019	Pass

Substantial Equivalence Conclusion Statement

The Sensus TPS Workstation has the same intended use as the predicate device. Any technological changes to the device do not raise new questions of safety or effectiveness. Performance testing, along with verification and validation activities demonstrate that the Sensus Healthcare TPS Workstation is as safe and effective, and performs as well as the predicate device. Therefore, the Sensus Healthcare TPS Workstation can be considered substantially equivalent to the predicate device.

Attributes	*Sensus TPS Workstation (K182665)*	*Radiance V4 (K171885)*	Discussion
Manufacturer	Sensus Healthcare	GMV Soluciones Globales Internet S.A.U.	---
Classification	21 CFR 892.5050	21 CFR 892.5050	Equivalent
Product Code	MUJ	MUJ	Equivalent
Indications for Use	Sensus TPS Workstation is a software system intended for treatment planning and analysis of intraoperative radiation therapy administered with the Sensus IORT System, a device suitable for intraoperative radiotherapy. The treatment plans provide treatment unit set-up parameters and estimates of dose distributions expected during the proposed treatment, and may be used to administer treatments after review and approval by the intended user. The system functionality can be configured based on user needs. The intended users of Sensus TPS Workstation shall be clinically qualified radiation therapy staff trained in using the system.	Radiance V4 is a software system intended for treatment planning and analysis of intraoperative radiation therapy administered with devices suitable for intraoperative radiotherapy. The treatment plans provide treatment unit set-up parameters and estimates of dose distributions expected during the proposed treatment, and may be used to administer treatments after review and approval by the intended user. The system functionality can be configured based on user needs. The intended users of Radiance V4 shall be clinically qualified radiation therapy staff trained in using the system.	Equivalent
System Design	Software only	Software only	Equivalent
Calculation for electrons	N/A	Dose distributions computed using a three dimensional dose engine. Pencil Beam computation and Monte Carlo Computation for electrons	Although the predicate is compatible with both IORT and IOERT devices, the Sensus Healthcare TPS Workstation is only compatible with the Sensus IORT device, and so does not support calculations for electrons.
Calculation for photons	Use of pre-calculated Monte Carlo simulations for the Sensus IORT System	Dose Painting (Planning calculation interpolation of PDD measurements) and Hybrid Monte Carlo computation for INTRABEAM.	A set of Monte Carlo simulations has been performed to predict the dose distribution produced by each operating point of the Sensus IORT device with high accuracy. These pre-calculated dose

Attributes	*Sensus TPS Workstation (K182665)*	*Radiance V4 (K171885)*	Discussion
			distributions are used by the Sensus Healthcare TPS Workstation to calculate the combination of operating points that most closely matches the target treatment dose distribution. This calculation is performed using a global optimization algorithm.
Input	Externally acquired patient medical images and user input. Calibration files and beam modeling measurements for Sensus IORT System	Externally acquired patient medical images and user input. Calibration files and beam modeling measurements for INTRABEAM	Equivalent
Output	Treatment plans with corresponding dose distributions	Treatment plans with corresponding dose distributions	Equivalent
Plan review and approval	Allows electronic approval of treatment plans by trained and authorized staff	Allows electronic approval of treatment plans by trained and authorized staff	Equivalent
Dose calculation algorithm confirmation	Algorithms confirmed for a wide variety of field geometries, treatment units, treatment setups and patient positions, including different dose grid resolution settings.	Algorithms confirmed for a wide variety of field geometries, treatment units, treatment setups and patient positions, including different dose grid resolution settings.	Equivalent
Beam modeling tool	Beam modeling of the treatment unit based on relative measurements and output factors.	Beam modeling of the treatment unit based on relative measurements and output factors.	Equivalent