February 21, 2019

% Mr. Nicolas Soro
QA/RA Manager
851 Broken Sound Parkway NW
Suite 215
BOCA RATON FL 33487

Re: K182641
Trade/Device Name: Sensus IORT System
Regulation Number: 21 CFR 892.5900
Regulation Name: X-ray radiation therapy system
Regulatory Class: Class II
Product Code: JAD
Dated: December 27, 2018
Received: January 22, 2019

Dear Mr. 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 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)*
K182641

Device Name

Sensus IORT System

Indications for Use *(Describe)*
The Sensus IORT System is indicated for radiation therapy treatments. The Sensus IORT System is an electron linear accelerator with a beam-forming x-ray target used for low energy radiation therapy to treat lesions, tumors, and conditions in or on the body where radiation is indicated.

Only Sensus TVM Balloon Applicators can be used with the Sensus IORT 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, CTO
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Date Summary Prepared: September 18, 2018

Device Name: Trade/Proprietary Name – Sensus IORT System

Common/Usual Name – Intraoperative Radiation Therapy System

Classification Name – X-ray Radiation Therapy System (892.5900)

Classification: Class II

Product Code: JAD

Regulation Number: 892.5900

Predicate Device: Xoft Axxent Brachytherapy System (K153570)

Device Description

The Sensus IORT System is a mobile robotically-guided low-energy intraoperative radiotherapy device for treating cancer lesions and tissue beds during and post-surgery. The X-ray source with beam shaping Morpheus provides radiation emission in the low energy therapy ranges of 50, 60, and 70 kV (a total of 3 kV modes) and is held and moved in place by an IEC 60601 medical certified robotic-arm. The robotic-arm uses a 7-axis motion system and is designed for human-robot collaboration for optimized treatment delivery and dosimetry.

The robotic-arm and its control cabinet mounted in the base of the Sensus IORT System contains multiple sensory capabilities for safety and simple operator control that allows it to act as an assistant to the doctor. The robot's joint torque sensors allow it to touch the patient with enough sensitivity to move with respiratory tracking (dubbed Cybernetic Respiratory Motion Tracking, or CRMT) and allow hand-guided movement by the doctor to control and place the x-ray source into position to deliver therapy.

The X-ray source held by the robotic arm consists of a drift tube and electron acceleration stage. In general, kilovoltage x-ray sources produce x-rays by accelerating electrons onto a tungsten target, which is a high-Z material. The electrons decelerate in the target, and their energy is converted to x-ray radiation (referred to as Bremsstrahlung, literally "braking" radiation), which is emitted in a roughly isotropic radiation pattern.

The Morpheus x-ray gun enables the Sensus IORT System to deliver an optimal and effective therapy beam to the targeted tissue bed that requires localized treatment. The Morpheus x-ray gun is operated by the system's control circuits and software and it is being fed by the high voltage power supply (HVPS), which provides the high voltage through the HV Feedthrough to

the Morpheus x-ray gun and the integrated cooling module, which circulates the cooling fluid in order to maintain the Morpheus x-ray gun at a stable and optimal thermodynamic condition. The currently available kV modes of the Morpheus x-ray gun are 50kV, 60kV, and 70kV (Gen 1.0). The high voltage potential from the HVPS is fed to the Cathode by the HV Feedthrough onto the Cathode Assy.

Once the electron beam hits the Diamond-Tungsten-Molybdenum (CW-Mo) target, x-ray photons are generated in an isospheric pattern that is emitted towards the front and back of the target. The x-ray photons have no attenuating barrier in the front of the target (the attached Cooling Jacket is x-ray translucent) and the x-ray photons that are emitted from the back side of the target are emitted out with no significant attenuation through the SiC Window Sleeve. This allows the x-ray photons to be effectively generated and emitted from both sides of the target, thus rendering an optimal geometric distribution and coverage of the generating x-ray beam to deliver therapy.

The system base unit is self-propelled with full battery backup, which allow the operators to move it between surgical suites and hospital facilities. It also features a 3KW back up UPS, which allows the operators to complete a full treatment, even if the hospital power grid goes off line.

The Sensus IORT System is a stand-alone system that incorporates its own cooling module, power supplies, and networking. It consists of five separate core components:

- Computer Control Console
- Beam Shaping Morpheus / X-Ray Source (to delivery X-ray radiation)
- Cybernetic Respiratory Motion Tracking (using the Robotic Arm)

- Base Unit with Drive/Propulsion System (device cabinet with motor)
- Red-Diode laser for positioning

The Sensus IORT System X-ray source interacts with a sterile tissue volume management (TVM) Balloon Catheter to act as a barrier between the X-ray source and the patient.

Indications for Use:

The Sensus IORT System is indicated for radiation therapy treatments. The Sensus IORT System is an electron linear accelerator with a beam-forming x-ray target used for low energy radiation therapy to treat lesions, tumors, and conditions in or on the body where radiation is indicated. Only Sensus TVM Balloon Applicators can be used with the Sensus IORT System.

Prescriptive Statement

The Sensus IORT System is intended for use by a physician and other specially-qualified individuals properly trained in the system's use and application.

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

Technological Characteristics/Principles of Operation

The Sensus IORT System produces and emits filtered, low energy (50, 60, and 70 kV) x-ray radiation, which is electrically generated using the onboard Kimball Power Supply and HV Generator (also referred to as HV Power Supply).

The X-ray source consists of a drift tube and electron acceleration stage. In general, kilovoltage x-ray sources produce x-rays by accelerating electrons onto a tungsten target, which is a high-Z material. The electrons decelerate in the target, and their energy is converted to x-ray radiation (referred to as Bremsstrahlung, literally "braking" radiation), which is emitted in a roughly isotropic radiation pattern.

For the Sensus IORT System IORT, the x-ray target is located inside the drift tube at the tip, which is placed inside the patient enabling direct exposure of the tissue under treatment. It is generally desirable to irradiate the tissue bed under treatment while sparing other anatomical structures that are not under treatment.

To hold the x-ray source in place, the Sensus IORT System utilizes a medical robot which was designed for human collaboration and incorporates numerous safety features built-in. This robot has been tested to and passed the ISO 13849 standard of safety for machinery, and IEC 60601-1 safety tests for medical devices. Torque settings of the 7-axis arm will allow for tracking of patient respiration and will yield if it encounters excessive force utilizing a collision detection mechanism. The robot also allows for extreme accuracy with a position repeatability of $\pm$ 0.15 mm (ISO 9283). Once the robot is activated for "hold position", the robot will return to this position within this tolerance.

Summary of Non-Clinical Performance Testing

The Sensus Healthcare Sensus IORT System, as configured, has been engineered and tested to meet Sensus Healthcare product requirements, required electrical and mechanical safety standards, and meet clinical expectations. All testing of the Sensus IORT System was performed in accordance with defined test cases with clearly delineated acceptance criteria. Additionally, FDA consensus standards and recognized ISO and IEC standards (e.g., IEC 60601-1 3rd edition) were employed for the bench testing, functional testing, and overall system performance testing of the Sensus IORT System. Furthermore, all testing was commissioned to qualified and accredited independent laboratories.

Non-clinical Safety Tests

The Sensus Healthcare IORT System has been designed and constructed to meet the following electrical and mechanical safety standards:

- IEC 60601-1:2005 Ed.3+A1; C1: 2014 – Medical Electrical Equipment – Part 1: General Requirements For Basic Safety And Essential Performance
- AAMI ES60601-1:2005 +A1:2012 – Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance
- CSA C22.2#60601-1:2014 Ed.3 – Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance
- IEC 60601-1-2:2007 Part 1: General requirements for safety. Collateral standard: electromagnetic compatibility – requirements and tests
- IEC 60601-1-6:2010 Ed.3+A1 – Medical Electrical Equipment - Part 1-6: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Usability
- IEC 60601-2-8:2010 Ed.2+A1 – Medical Electrical Equipment - Part 2-8: Particular Requirements For Basic Safety And Essential Performance Of Therapeutic X-Ray Equipment Operating In The Range 10 Kv To 1 Mv

- IEC 62366:2007 Ed.1+A1 – Medical Devices - Application Of Usability Engineering To Medical Devices

- IEC 60825-1:2007 – Safety of laser products – Part 1: Equipment classification and requirements

The Sensus IORT system has been tested to the following safety tests for IEC 60601:

TEST STANDARD	TEST	REPORT
IEC 60601-1:2005 Ed.3+A1;C1:2014	Medical Electrical Equipment – Part 1: General Requirements For Basic Safety And Essential Performance	103306090MIN-001
IEC 60601-1:2005 Ed.3+A1;C1:2014	Medical Electrical Equipment – Part 1: General Requirements For Basic Safety And Essential Performance	103306090MIN-001
IEC 60601-1:2005 Ed.3+A1;C1:2014	Medical Electrical Equipment – Part 1: General Requirements For Basic Safety And Essential Performance	103306090MIN-001
IEC 60601-2-8:2010Ed.2+A1	Medical Electrical Equipment - Part 2-8: Particular Requirements For Basic Safety And Essential Performance Of Therapeutic X-Ray Equipment Operating In The Range 10 Kv To 1 Mv	103306090MIN-002
IEC 60601-1-6:2010Ed.3+A1	Medical Electrical Equipment - Part 1-6: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Usability	103306090MIN-003
IEC 60601-1-2 Issued: 2007/03/30 Ed: 3	Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility - Requirements & Tests	103306090MIN-009
IEC 60825-1:2007	Safety of laser products – Part 1: Equipment classification and requirements	101125082BOX-009

Table 1 IEC 60601 Safety Testing Sensus IORT System

REPORT	TEST NAME
6-2-5400-0000	Cybernetic Respiratory Motion Tracking (CRMT) Testing Protocol
6-2-5401-0000	Cybernetic Respiratory Motion Tracking Testing Report
6-2-5410-0000	Sterile drape compatibility testing protocol
6-2-5411-0000	Sterile drape compatibility testing report
6-2-5380-0000	Verification & Validation report
6-2-5381-0000	IORT Base Software Verification & Validation Test Plan

Table 2 Verification and Validation Testing

The Sensus IORT system utilizes a Robotic Arm to hold and position the X-ray source to help assist in delivering treatment. The robotic arm has been tested to the following safety tests for IEC 60601:

TEST STANDARD	TEST	REPORT
IEC 60601-1:2005 (Third Edition) + CORR. 1:2006 + CORR. 2:2007 + A1:2012	Medical Electrical Equipment – Part 1: General Requirements For Basic Safety And Essential Performance	215755-CI2-2
IEC 62304:2006	Medical device software - Software life-cycle processes	215755-CI2-3

Substantial Equivalence Discussion

Sensus Healthcare has conducted a detailed comparison of the Sensus IORT System IORT versus the predicate device. The results of the comparison are listed below in the comparison table below.

Attributes	*Sensus Healthcare IORT System*	*Xoft Axxent (Predicate)*	Discussion
Intended Use	*Radiation therapy*	*Radiation therapy*	Equivalent to predicate
Indications for Use	*The Sensus IORT System is high dose rate Brachytherapy device for use with Morpheus TVM Applicators to treat lesions, tumors and conditions in or on the body where radiation is indicated. Only Sensus TVM Balloon Applicators can be used with the Sensus IORT System.*	*The Axxent® Electronic Brachytherapy System Model 110 XP 1200 is a high dose rate Brachytherapy device for use with Axxent Applicators to treat lesions, tumors and conditions in or on the body where radiation is indicated.*	Equivalent to predicate
Regulation Name	*Electronic brachytherapy system*	*Electronic brachytherapy system*	Equivalent to predicate
Regulation	*21 CFR 892.5900, Class II*	*21 CFR 892.5900, Class II*	Equivalent to predicate
Product Code	*JAD: System, Therapeutic, X-Ray*	*JAD: System, Therapeutic, X-Ray*	Equivalent to predicate
Use Environment	*Operating room or practitioner's office*	*Operating room or practitioner's office*	Equivalent to predicate
Therapy type	*X-Ray Photon*	*X-Ray Photon*	Equivalent to predicate
X-Ray source operation mode	*Electrons are emitted by cathode, accelerated by an electrical field along a drift tube inside the X-Ray source and hit a tungsten target resulting in the generation of X-rays*	*Electrons are emitted by cathode, accelerated by an electrical field along a drift tube inside the X-Ray source and hit a tungsten target resulting in the generation of X-rays*	Equivalent to predicate
Method of treatment / application	*Intraoperative* *Intracavitary* *Interstitial* *Post-Operative*	*Intraoperative* *Intracavitary* *Interstitial* *Post-Operative*	Equivalent to predicate
X-Ray Source Kilo-Voltage Modes	*50, 60, 70 kV*	*30, 40, 50 kV*	The kV impacts the dose rate but does not change the penetration rate according to the source dosimetric

Attributes	*Sensus Healthcare IORT System*	*Xoft Axxent (Predicate)*	Discussion
			characterization report. Reference report SEN19068. The 50-70 kV mode of the Sensus IORT System has a similar penetration rate as the predicate's 50 kV mode.
X-Ray Source Current	*Beam currents of 720 uA at 70 kV up to 1.00 mA at 50 kV*	*Up to 300uA, which is the maximum current of the X-ray tube over the entire kilovoltage range of 30, 40, and 50kV*	*Similar to predicate; Enhanced.* *Due to different source technology and architecture between the predicate and the Sensus IORT System, the x-ray source current is different due to the respective method, geometry, and materials applied for each source design.* *In spite of the different source currents between the Sensus IORT System and the predicate, the resulting beam output and physics are comparable.*
Geometry of dose emitted (without applicator)	*Mostly spherical*	*Mostly spherical*	*Equivalent to predicate*
Maximum Radiation Output	*400 – 1000 cGy/min (at 4cm – 3cm from isocenter, respectively)*	*60 cGy/min (at 3cm from isocenter)*	*Although the Sensus IORT System employs equivalent beam-formation physics and science, it has faster and more effective dose rate due to a variable kV range, different electron gun design, and target materials and design.*
Maximum Power Range	*50W (70kV x 0.720 uA)*	*15W (50kV x 300uA)*	*Due to different x-ray source technology and architecture between the predicate and the Sensus IORT System, the power output of each comparable source is different due to the respective designs and Bremsstrahlung beam generation methods, geometry, and materials applied in each respective x-ray source* . *In spite of the different power ratings between the Sensus IORT System and the predicate, the resulting beam output and physics are comparable.*
kV Control	*Microprocessor*	*Microprocessor*	Equivalent to predicate
mA Control	*Microprocessor*	*Microprocessor*	Equivalent to predicate
Primary Exposure Timer	*Microprocessor*	*Microprocessor*	Equivalent to predicate
Secondary (Backup) Exposure Timer	*Yes - Microprocessor*	*Yes – Microprocessor*	Equivalent to predicate
Timer Monitoring and Safety Shutoff	*Yes - Hardware*	*Yes – Hardware*	Equivalent to predicate
Safety Interlocks	*Interlock to prevent unintended radiation* *Interlock to prevent unintended access to the controlled area* *Interlock to prevent incorrect radiation data transmission* *Robotic manipulator safety interlocks*	*Interlock to prevent unintended radiation* *Interlock to prevent unintended access to the controlled area* *Interlock to prevent incorrect radiation data transmission*	Similar to predicate for the safety interlocks on the device to deliver therapy. Additional safety interlocks for the robotic manipulator are available on the Sensus IORT System to help ensure patient and operator safety during operation, similar to reference device.
X-ray Tube Target	*Tungsten*	*Tungsten*	Similar to predicate, both tungsten (W) and gold (Au) targets use

Attributes	*Sensus Healthcare IORT System*	*Xoft Axxent (Predicate)*	Discussion
			bremsstrahlung method for generation of x-rays. Tungsten (W) is similar to gold (Au) and very common in the industry for production of x-rays.
Dose fall-off (in water)	*~1/r^3*	*~1/r^3*	Equivalent to predicate
Mobility	*Yes – propulsion drive*	*Yes - manual*	Similar to predicate; enhanced Both devices are mobile, however the Sensus IORT System features a self-propulsion system.
Robotic manipulator arm delivery system	*7-axis robotic manipulator mounted at the front of the Sensus IORT System's base. Load capacity of the robotic manipulator is 14 kg (31.86 lbs).* *Robotic manipulator developed by Kuka Robotics.*	*N/A* *Note: X-ray source is inserted manually into the Axxent applicator.*	Different from predicate. Sensus IORT System uses a 7-axis portable robotic manipulator with a load capacity of 31.86 lbs vs the predicate device, which requires manual insertion and manipulation. The Sensus IORT System's integration of robotics enhances the precision and radiation treatment delivery means vs. the predicate device through the introduction of the dexterity and accuracy of the robot.
Performance Standards Tested	*IEC60601-2-8 Standard for Radiation Therapy Devices*	*IEC60601-2-8 Standard for Radiation Therapy Devices*	Equivalent to predicate
Electrical Safety Standards Tested	*IEC60601-1-2*	*IEC60601-1-2*	Equivalent to predicate
Applicators Use	*Disposable*	*Disposable*	Equivalent to predicate
Compatible Applicators	*Sensus Morpheus TVM Balloon Catheter Applicator (concurrent separate 510(k) submission)*	*Xoft Axxent Applicators (separate 510(k) submission – K090914)*	Equivalent to predicate
Red-Diode Laser Pointing Capability	*Red-Diode Laser* *U.S. Laser, Inc. (Item M650-5CH-V2)* *FDA Laser Class: 3A; IEC Laser Class: 3R* *FDA Accession #: 95R2254* *Wavelength: 650nM* *Max Power: 5mW* *Beam Divergence: 15 deg max*	*N/A*	The laser on the Sensus IORT System is only to aide physicians/operators in positioning and placement of the x-ray source apparatus during preparation for treatment.
Treatment Planning System	Yes	Yes	Equivalent to predicate Separate 510(k) submissions.

Table 3 Substantial Equivalent Comparison

The Sensus IORT System is substantially equivalent to the predicate, the Xoft Axxent Brachytherapy System, due to the amount of similar key performance characteristics such as the indications for use, x-ray photons therapy modality, the emission of electrons using cathodes, and the spherical geometry of the emitted dose.

The primary differences of the Sensus IORT System vs the predicate include a broader energy kV range of 50, 60 and 70 kV, a tungsten target vs a gold target on the predicate (which are both widely used as x-ray generation target materials employing the bremsstrahlung phenomenon), a higher dose rate, and an x-ray source mounted on a robotic manipulator arm vs the source mounted on a manually manipulated mechanical arm on the predicate.

In addition to helping the physician manipulate and positioning the x-ray source, the robotic manipulator arm offers a respiratory motion tracking functionality to follow the patient's respiratory motion during the procedure, thus optimizing the therapy delivery.

Conclusion Statement

All the Sensus IORT System's intended use can be found in the intended use of the predicate device and reference device. Any technological changes to the device are minor, primarily as it pertains to industrial design, and do not raise new questions of safety or effectiveness. The primary difference between the Sensus IORT System and its predicate is the use of the robotic manipulator arm to control and provide a stable delivery of the radiation therapy. 0Safe use and approval of a similar robotic manipulator with a radiation delivery system are found in the reference device which utilizes a 6-axis robotic manipulator developed by the same robotics manufacturer as utilized by Sensus Healthcare. Performance testing, along with verification and validation activities demonstrate that Sensus IORT System is as safe and effective, and performs as well as the predicate device. Therefore, Sensus IORT System can be considered substantially equivalent to the predicate device.