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

March 23, 2018

Re: K173425
Trade/Device Name: SRT-100+
Regulation Number: 21 CFR 892.5900
Regulation Name: X-ray radiation therapy system
Regulatory Class: II
Product Code: JAD
Dated: February 23, 2018
Received: February 26, 2018

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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)*
K173425

Device Name
SRT-100+

Indications for Use *(Describe)*
The SRT-100+ System is a low energy x-ray system, intended for superficial radiotherapy treatments of primary malignant epithelial neoplasms of the skin and keloids. Applications include: (a) basal cell carcinoma; (b) squamous cell carcinoma; (c) Metatypic carcinoma; (d) cutaneous appendage carcinoma (e) Kaposi's Sarcoma; and (f) the treatment of keloids. Keloids are benign fibrous growths that arise from proliferation of dermal tissue typically arising from injuries to skin tissue.
A red-diode laser is employed for the assisting with cone applicator placement.

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

510(k) SUMMARY

[As Required by 21 CFR 807.92(c)]

Submitter's Name & Address: Sensus Healthcare
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Date Summary Prepared: March 19, 2018

Device Name: Trade/Proprietary Name – SRT-100+

Common/Usual Name – Superficial X-ray Radiation Therapy System

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

Classification: Class II

Product Code: JAD

Regulation Number: 892.5900

Predicate Device: Sensus Healthcare SRT-100 Vision (K150037)

Reference Devices: Sensus Healthcare SRT-100 (K123985)

Previous FDA Submissions & Clearances

Table 1.0 contains a compilation of previously cleared versions of the SRT-100 and SRT-100 Vision Systems.

Table 1.0 – Previously Cleared SRT-100 Systems

Clearance	Date	Class	Product Code	System	Indications for Use
K150037	16 October 2015	II	JAD	SRT-100 Vision	The SRT-100 Vision is a low energy x-ray system, with ultrasound imaging and red-diode laser capabilities, intended for superficial radiotherapy treatment of primary malignant epithelial neoplasms of the skin and keloids.
K131582	28 August 2013	II	JAD	SRT-100 Vision	The SRT-100 Vision is a low energy x-ray system, with ultrasound imaging and red-diode laser capabilities, intended for superficial radiotherapy treatment of primary malignant epithelial neoplasms of the skin and keloids.
K123985	14 May 2013	II	JAD	SRT-100	The SRT-100 is a low energy x-ray system intended for superficial radiotherapy treatment of primary malignant epithelial neoplasms of the skin and keloids.
K063456*	9 January 2007	II	JAD	SRT-100	The SRT-100 is a low energy x-ray system intended for superficial radiotherapy treatment of primary malignant epithelial neoplasms of the skin.

Note: This original clearance was provided to Topex, Inc. in 2007. It was also the predicate device referenced for the Esteya System.

Device Description

The Sensus Healthcare SRT-100+ is a complete, stand-alone, x-ray radiation therapy system. It consists of four separate components: (a) control console; (b) base unit; (c) red-diode laser; and (d) applicators.

(a) ***Control Console:*** Specifically designed module housing the switches and indicators used by the operator to set up and execute x-ray exposures. The controls adjust the machine functions and settings only! There is no treatment planning capability. The Control Console is connected, through a cable, to the Base Unit.

(b) ***Base Unit:*** The base unit consists of a cabinet containing the high voltage generator, power supply components, cooling system, and an arm/positioning mechanism on which the x-ray tube housing assembly is mounted. A series of Applicators are included, which are affixed to the x-ray port on the x-ray tube housing assembly to limit the x-ray beam and provide fixed Source-to-Skin Distance (SSD). The X-ray Tube-Housing Assembly contains a motorized filter mechanism, which moves the appropriate beam filter: (a) 0.10 mm Al at 20 to 30 kV; (b) 0.45 mm Al at 50kV; (c) 0.75 mm Al at 70 kV; and (d) 1.15 mm Al at 100 kV; into the beam path depending on the kV setting selected by the operator.

(c) ***Red-Diode Laser:*** A red-diode laser is integrated with the SRT-100+ System. The laser is manufactured by U.S. Laser and is classified as FDA Laser Class 3A. The application of the red-diode laser with the Sensus SRT-100 Vision has been tested in accordance with IEC 60825-1.

(d) ***Applicators:*** The system is shipped with a set of interchangeable treatment applicators, which define the source to skin distance (SSD) and the diameter of the

treatment beam's exposure. The applicator size, therefore, determines the amount of total dose delivered per minute to the lesion and the actual area that will be treated by the system's x-ray beam. Each applicator is embedded with a unique magnet binary combination, which allows the system to automatically detect an applicator as it is mounted on the x-ray port. This provides the system with the information about the applicator's SSD and diameters, which allows it to correlate the applicable dose rate for each applicator that is attached to the x-ray port, thus allowing for a precise and user-error-free dose rate per minute calculation. There are a variety of applicator sizes available for use with the Sensus Healthcare SRT-100+ System, driven by the treatment modality.

Indications for Use:

The SRT-100+ System is a low energy x-ray system, intended for superficial radiotherapy treatments of primary malignant epithelial neoplasms of the skin and keloids. Applications include: (a) basal cell carcinoma; (b) squamous cell carcinoma; (c) Metatypic carcinoma; (d) cutaneous appendage carcinoma (e) Kaposi's Sarcoma; and (f) the treatment of keloids. Keloids are benign fibrous growths that arise from proliferation of dermal tissue typically arising from injuries to skin tissue.

A red-diode laser is employed for the assisting with cone applicator placement.

Prescriptive Statement

The SRT-100+™ System is intended for use by a physician and other specially-qualified individuals properly trained in the system's use, science, and application.

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

Technological Characteristics/Principles of Operation

The SRT-100+ produces and emits filtered, low energy (20, 30, 50, 70, and 100 kV) x-ray radiation, which is electrically generated using a conventional metal ceramic x-ray tube (Comet MXR-100). Provision is made to limit the x-radiation to a specified treatment field, and to control the radiation dose to the patient through selection and monitoring of energy, emission level and duration of emission. To mitigate effects of ionizing radiation on healthy cells, and to accumulate more damage in the neoplastic cells and keloids associated with scar tissue, the total dose is fractionated, which means distributing the total dose over a period of time. Typically, 8 to 12 fractions at a rate of 1 to 5 per week are used to deliver a total dose of 40-60 Gy, although larger PMENs may require up to 40 fractions over an 8-week period for a total dose of 80 Gy. When treating keloids, typically 1 to 4 fractions are employed, delivering a total dose in the range of 10 to 40 Gy.

Review of Clinical Literature

A summary of multiple clinical studies for the treatment of keloids and supporting literature has been collected, reviewed, and a clinical evaluation report scripted in support of this 510(k). The literature collected and reviewed supports Sensus Healthcare's claims of safety and efficacy for the application of superficial radiotherapy treatments of primary malignant epithelial neoplasms of the skin and keloids. Applications include: (a) basal cell carcinoma; (b) squamous cell carcinoma; (c) Metatypic carcinoma; (d) cutaneous appendage carcinoma (e) Kaposi's

Sarcoma; and (f) the treatment of keloids. Keloids are benign fibrous growths that arise from proliferation of dermal tissue typically arising from injuries to skin tissue.

Summary of Non-Clinical Performance Testing

All of the Sensus Healthcare SRT-100+ capabilities are also found in the previously cleared SRT-100 Vision System predicate device; and similar capabilities. The Sensus Healthcare SRT-100+ 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 SRT-100+ 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 SRT-100+. Furthermore, all testing was performed by qualified and accredited independent laboratories.

Non-clinical Safety Tests

The Sensus Healthcare SRT-100+ 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

Substantial Equivalence Discussion

Sensus Healthcare SRT-100 Vision (K150037)

The SRT-100+ was designed using the critical components of the SRT-100 Vision system, including the same X-ray tube for delivery of radiation and the same control boards/PCBs that control the unit. The SRT-100+ has a contracted indication for use when compared to the SRT-100 Vision with the removal of the imaging capabilities (ultrasound module) and a removal of the electronic brachytherapy treatment. Functionally, the unit can perform radiation emissions in the 20, 30, 50, 70, or 100 kV range as opposed to the Vision's larger 20, 30, 50, 60, 70, 80, 90, or 100 kV range. Furthermore, the SRT-100+ has four (4) filtration options vs six (6) filtration options on the SRT-100 Vision. The unit has an articulating arm similar to the predicate device that is used to position the X-ray head for delivery of therapy. During treatment, the same applicators and applicator tips that are attached to the X-ray head of the SRT-100 Vision are used on the SRT-100+. The device is similar in size, dimensions, and

weight where both devices are mounted on a baseplate attached to castors for ease of mobility and positioning during installation and operation of the device.

Sensus Healthcare SRT-100 (K123985)

The SRT-100 system was originally designed by Topex Inc. and cleared under 510(k) K063456 on January 09, 2007. The Topex SRT-100 and associated intellectual properties (IP) were acquired by Sensus Healthcare in 2010. The SRT-100 user requirements were reviewed along with the SRT-100 Vision user requirements during the development of the SRT-100+ system. Functionally, the SRT-100 can perform radiation emissions in 50, 70, or 100 kV range as opposed to the SRT-100+'s expanded 20, 30, 50, 70, or 100 kV range. The core functionality of the SRT-100+ is very similar to the SRT-100 including comparable size, weight, and dimensions, but ultimately the SRT-100 Vision was chosen as the predicate device due to similarity of subcomponents used in the device.

Conclusion Statement

All the SRT-100+ 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. Performance testing, along with verification and validation activities demonstrate that SRT-100+ is as safe and effective, and performs as well as the predicate device. Therefore, SRT-100+ can be considered substantially equivalent to the predicate device.