K131582
Page 1 of 5
ORIGINAL

Section Five (5) - 510(k) Summary

510(k) SUMMARY

[As Required by 21 CFR 807.92(c)]

AUG 28 2013

Submitter's Name & Address:

Sensus Healthcare
851 Broken Sound Parkway NW
Suite 215
Boca Raton, FL 33487

Contact Person:

Kal Fishman, COO
Telephone (423) 404-4891
Fax (561) 948-2071
kal@sensushealthcare.com

Date Summary Prepared: May 29, 2013

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

Common/Usual Name – Superficial X-ray Radiation Therapy System with Ultrasonic Imaging and Red-Diode Laser Pointing Capabilities

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

Predicate Device – Sensus Healthcare SRT-100 (K123985)

Reference Device – Cortex Technology Derma-Scan C Ultrasound System (K983945)

ORIGINAL

Device Description:

The Sensus Healthcare SRT-100 Vision is a complete, stand-alone, X-ray radiation therapy system, with ultrasound capability. It consists of four major separate components:

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.

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 into the beam path depending on the kV setting selected by the operator.

Ultrasound Imaging: The Derma-Scan C Ultrasound System component (manufactured by Cortex Technology) is integrated with the SRT-100 Vision System and contains: (a) scanning main unit; (b) handheld probe and (c) a medical grade power supply to provide power to the computer. The ultrasound component is designed and tested to meet international safety requirements.

Red-Diode Laser: A red-diode laser is integrated with the SRT-100 Vision 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.

Intended Use:

The SRT-100 Vision is a low energy X-ray system, with ultrasound imaging capability, is intended for superficial radiotherapy treatment of primary malignant epithelial neoplasms of the skin and keloids. Applications include basal cell carcinoma, squamous cell carcinoma, Metatypic carcinoma, cutaneous appendage carcinoma, Kaposi's Sarcoma, and the treatment of keloids. Keloids are benign fibrous growths that arise from proliferation of dermal tissue typically arising from injuries to skin tissue.

The ultrasound capability, employed in a non-diagnostic mode, is used to assist the physician in identification of lesion location; and the selection of the correct cone applicator size and energy mode required for delivery of therapy. The Derma-Scan C Ultrasound component was initially cleared with an indication for use as an ultrasonic scanning system used to visualize the layers of skin, including bold vessels, and to make approximate measurements of dimensions in layers of skin and blood vessels, by ultrasonic means.

A red-diode laser is employed for the assisting with cone applicator placement. 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. The test results can be found in Appendix J of this 510(k).

Prescriptive Statement

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

Technological Characteristics/Principles of Operation:

The SRT-100 Vision produces and emits filtered, low energy (50, 70 and 100 kV) x-radiation, which is electrically generated using a conventional ceramic X-ray tube. 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.[1] (Panizzon, R and Cooper, J. (Eds.) Radiation Treatment and Radiation Reactions in Dermatology, Springer Verlag, 2004, p. 75). When treating keloids, typically 1 to 4 fractions are employed, delivering a total dose in the range of 10 to 40 Gy. A summary of multiple clinical studies for the treatment of keloids and supporting literature can be found in Appendix D of this 510(k).

Non-Clinical Performance Testing:

Performance testing consisted of bench testing that has demonstrated that the output of the Sensus Healthcare SRT-100 Vision provided the same clinical capabilities as the predicate device. The system successfully passed all tests required by *IEC 60601-1, Part 2-8, Edition 1.1, 1999 – Particular Requirements for the Safety of Therapeutic X-ray Equipment Operating in the Range 10 kV to 1 MV* and also tests developed internally for system characterization.

Additional performance testing was executed to validate the operational characteristics associated with the Sensus Applicators. Schematics of the applicators and associated performance curves are located in appendix E of this 510(k). The ultrasound component has been

tested in accordance with IEC 60601-2-37. The red-diode laser integrated with the Sensus SRT-100 Vision has been tested in accordance with IEC 60825-1. The test results, the addition of the ultrasound capability and red-diode laser pointing can be found in Appendix J of this 510(k).

Non-clinical Safety Tests:

The Sensus Healthcare SRT-100 Vision has been designed and constructed to meet the following electrical and mechanical safety standards:

- IEC 60601-1: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (2nd edition)
- UL 60601-1: Medical Electrical Equipment, Part 1: General Requirements for Safety
- CAN/CSA-C22.2 NO. 601.1-M90 (R2005): Medical Electrical Equipment, Part 1: General Requirements for Safety
- IEC 60601-1-2: medical equipment – Part 1: General requirements for safety. Collateral standard: electromagnetic compatibility – requirements and tests
- IEC 60601-1-4: Medical electrical equipment--Part 1-4: General requirements for safety – Collateral Standard: Programmable electrical medical systems
- IEC 60601-2-8: Medical equipment – Part 2-8: Particular requirements for the safety of therapeutic X-ray equipment operating in the range 10 kV to 1MV
- IEC 60601-2-32: Medical electrical equipment Part 2: Particular requirements for the safety of associated equipment of X-ray equipment
- IEC 60601-2-37: Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment
- IEC 60825-1: Safety of laser products – Part 1: Equipment classification, requirements and user's guide

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 28, 2013

Sensus Healthcare
% Mr. Kal Fishman
Chief Operating Officer
851 Broken Sound Parkway NW, Suite 215
BOCA RATON FL 33487

Re: K131582
Trade/Device Name: Sensus Healthcare SRT-100 Vision
Regulation Number: 21 CFR 892.5900
Regulation Name: X-ray radiation therapy system
Regulatory Class: II
Product Code: JAD
Dated: May 29, 2013
Received: June 4, 2013

Dear Mr. Fishman:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact 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/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Michael D. O'Hara for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K131582

Device Name: Sensus Healthcare SRT-100 Vision

Indications for Use:

The SRT-100 Vision is a low energy X-ray system, with ultrasound imaging and red-diode laser-pointing capabilities, intended for superficial radiotherapy treatment of primary malignant epithelial neoplasms of the skin and keloids. Applications include basal cell carcinoma, squamous cell carcinoma, Metatypic carcinoma, cutaneous appendage carcinoma, Kaposi's Sarcoma, and the treatment of keloids. Keloids are benign fibrous growths that arise from proliferation of dermal tissue typically arising from injuries to skin tissue.

Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

Michael D. O'Hara

(Division Sign Off)
Division of Radiological Health
Office of *In Vitro* Diagnostic and Radiological Health

510(k) K131582