SIT SORDINA IORT TECHNOLOGIES SPA
% Maurizio Pantaleoni
CEO
Isemed Srl
Via P. Togliatti, 19/X
Imola, Bo 40026
ITALY

June 11, 2018

Re: K172961
Trade/Device Name: LIAC HWL
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: May 8, 2017
Received: May 10, 2017

Dear Maurizio Pantaleoni:

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)*
K172961

Device Name
LIAC HWL

Indications for Use *(Describe)*
LIAC HWL are mobile electron linear accelerators for intra-operative radiotherapy (IORT). Known as intraoperative radiation therapy (IORT), this technique allows delivery of high doses of radiation directly aimed at tumors or other sites.
The LIAC HWL are meant to be used for radiotherapy in the operating theatre on a patient to which the surgeon has just removed a neoplasm.
The devices must be sold by or on the order of a physician. They are not for use by the general public or over-the-counter.

LIAC HWL are electron accelerators that can work in an operating theater respecting its specific characteristics in terms of cleaning possibility, noise and heat dissipation; in particular, they do not require to move the patient.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Traditional 510(k) Summary

This Traditional 510(k) Summary is being submitted as required by 21 CFR 807.92.

1. General Information

Submitter :

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Summary Prepared Date: November 24, 2017.

2. Names

Device Name: LIAC HWL
Common Name: Radiosurgery/radiotherapy treatment planning and delivery system
Regulation Name: Medical charged particle radiationtherapy system
Product Code: IYE
Classification: 21CFR 892.5050; Class II

3. Predicate Devices

The LIAC HWL is substantially equivalent to the following predicate devices, which are legally marketed in the US.

Applicant	Device name	510(k) Number
SIT SORDINA IORT TECHNOLOGIES SPA.	LIAC	K110840
	NOVAC11	K112286

The primary predicate device is LIAC (K110840) and secondary predicate device is NOVAC11 (K112286). Both devices are manufactured by SIT SORDINA IORT TECHNOLOGIES SPA. And they have not been subject of any device recalls.

LIAC HWL is a modified model of its primary predicate device LIAC (K110840). Both have the same intended use and the same operation mode. LIAC HWL and its predicate devices are electron linear Accelerators used to perform radiation therapy during surgical procedures in an operating room. This technique is known as Intra-Operative Radiation Therapy (IORT) ant it is used for the treatment of malignant and benign conditions. IORT allows delivering of high doses of radiation directly to tumour site, while normal tissues are protected against dosage impact.

SIT SORDINA IORT TECHNOLOGIES SPA was written this Traditional 510(k) for the LIAC HWL in accordance to "*Letter to Manufacturers of Linear Accelerators, Radiation Therapy Treatment Planning Systems, and Ancillary Devices*" released in 2010 by CDRH.

LIAC HWL (10MeV & 12 MeV) and LIAC (10MeV & 12 MeV) (K110840) have the following technological differences:

5. LIAC HWL has additional shielding system in the radiant head to reduce scattered radiation.
6. LIAC HWL has lower length applicators to reduce SSD.
7. LIAC HWL has a higher dose rate.
8. LIAC HWL and predicate device device LIAC (K110840) have a modified remote control.

SIT SORDINA IORT TECHNOLOGIES SPA has evaluated each modification of LIAC HWL to establish if the intended use or the technological features are different from those of predicate devices LIAC (K110840) and NOVAC 11 (K112286).

The differences between LIAC HWL and the predicate devices are summarized in the following comparison table:

Characteristic	**PROPOSE DEVICE**	**PREDICATE DEVICE**	
Device Name	LIAC HWL (MODELS: 10MEV AND 12MEV)	LIAC (MODELS: 10MEV AND 12MEV)	NOVAC11
			
	-	K110840	K112286
Manufacture	S.I.T. – SORDINA IORT TECHNOLOGIES SPA	S.I.T. – SORDINA IORT TECHNOLOGIES SPA	S.I.T. – SORDINA IORT TECHNOLOGIES SPA
GENERAL FEATURES			
Classification	II	II	II
Regulation number	892.5050	892.5050	892.5050
Product code	IYE	IYE	IYE
Product Code description	Accelerator, linear, medical Medical charged-particle radiation therapy system.	Accelerator, linear, medical Medical charged-particle radiation Therapy system	Accelerator, linear, medical Medical charged-particle radiation Therapy system

Indications for Use	LIAC HWL ARE MOBILE ELECTRON LINEAR ACCELERATORS FOR INTRA-OPERATIVE RADIOTHERAPY (IORT). KNOWN AS INTRAOPERATIVE RADIATION THERAPY (IORT), THIS TECHNIQUE ALLOWS DELIVERY OF HIGH DOSES OF RADIATION DIRECTLY AIMED AT TUMORS OR OTHER SITES. THE LIAC HWL ARE MEANT TO BE USED FOR RADIOTHERAPY IN THE OPERATING THEATRE ON A PATIENT TO WHICH THE SURGEON HAS JUST REMOVED A NEOPLASM. THE DEVICES MUST BE SOLD BY OR ON THE ORDER OF A PHYSICIAN. THEY ARE NOT FOR USE BY THE GENERAL PUBLIC OR OVER-THE-COUNTER. LIAC HWL ARE ELECTRON ACCELERATORS THAT CAN WORK IN AN OPERATING THEATER RESPECTING ITS SPECIFIC CHARACTERISTICS IN TERMS OF CLEANING POSSIBILITY, NOISE AND HEAT DISSIPATION; IN PARTICULAR, THEY DO NOT REQUIRE TO MOVE THE PATIENT.	LIAC (MODELS: 10MEV AND 12MEV) IS A MOBILE ELECTRON LINEAR ACCELERATOR FOR INTRA-OPERATIVE RADIOTHERAPY (LORT). KNOWN AS INTRAOPERATIVE RADIATION THERAPY (IORT), THIS TECHNIQUE ALLOWS DELIVERY OF HIGH DOSES OF RADIATION DIRECTLY AIMED AT TUMORS OR OTHER SITES. THE LIAC IS MEANT TO BE USED FOR RADIOTHERAPY IN THE OPERATING THEATRE ON A PATIENT TO WHICH THE SURGEON HAS JUST REMOVED A NEOPLASM. THE DEVICE MUST BE SOLD BY OR ON THE ORDER OF A PHYSICIAN. IT IS NOT FOR USE BY THE GENERAL PUBLIC OR OVER-THE-COUNTER.	NOVAC11 IS AN ELECTRON LINEAR ACCELERATOR USED FOR RADIATION THERAPY DURING SURGICAL PROCEDURES IN AN OPERATING ROOM FOR THE TREATMENT OF MALIGNANT AND BENIGN CONDITIONS. KNOWN AS INTRAOPERATIVE RADIATION THERAPY (IORT), THIS TECHNIQUE ALLOWS DELIVERY OF HIGH DOSES OF RADIATION DIRECTLY AIMED AT TUMORS OR OTHER SITES WHILE AVOIDING DOSAGE TO SURGICALLY MOBILIZED NORMAL TISSUES. NOVAC11 IS A MOBILE AND ARTICULATED MACHINE THAT CAN BE MOVED TOWARDS THE PATIENT AN PUT IN THE APPROPRIATE POSITION TO CARRY OUT THE NECESSARY RADIOTHERAPY. APPLICATORS LEAD THE ELECTRON BEAM TO THE SURGICAL AREA OF INTEREST.
DEVICE DESIGN – TECHNICAL FEATURES			
Design structure	• STAND (irradiating unit) • CONTROL UNIT • APPLICATORS	• STAND (irradiating unit) • CONTROL UNIT • APPLICATORS(ACCESSORY)	• STAND (irradiating unit) • CONTROL PANEL • APPLICATORS • PROTECTION DISC (ACCESSORY)
Emission	ELECTRON BEAM	ELECTRON BEAM	ELECTRON BEAM
Type of structure	LINAC	LINAC	LINAC
Docking	HARD DOCKING	HARD DOCKING	HARD DOCKING

Remote control	YES	YES	YES
Nominal energies	4, 6, 8, 10 MeV (10 MeV) 6 ,8 ,10 ,12 MeV (12 MeV)	4 ,6 ,8 ,10 MeV (10 MeV) 6, 8 ,10,12 MeV (12 MeV)	4,6,8,10 MeV
Maximum operating temperature	25°C	25°C	25°C
Maximum power dissipation	< 2.5 kW	< 2.5 kW	< 1 kW
Electrical power reqirement	230 V, 50 Hz, 3 kVA	230 V, 50 Hz, 3 kVA	230 V, 50 Hz, 2.5 kVA
Applied Standards	• IEC 60601-1 • IEC 60601-1-2 • IEC 60601-2-1 • IEC 62304	• IEC 60601-2-1 • IEC 60601-1 Rev.2nd (IEC 60601-1-4) • IEC 60601-1-2 • IEC 62304	• IEC 60601-1 • IEC 60601-1-2 • IEC 60601-1-4 • IEC 62304 • EN60601-2-1
DEVICE DESIGN – RADIATION PERFORMANCE			
Surface dose	≥ 88 % (10 MeV) ≥ 90 % (12 MeV)	≥ 85 % (10 MeV) ≥ 87 %(12 MeV)	≥ 80 - 85%
Field symmetry	≤ 3 %	≤ 3 %	≤ 2 %
Pulse repetition frequency	5 - 50 Hz (depended on the selected energy)	5 - 50 Hz (depended on the selected energy)	9 Hz
Beam current	≤ 1.5 mA	≤ 1.5 mA	≤ 1.5 mA
Long term stability	≤ 3 %	≤ 3 %	≤ 2 %
Short term stability	≤ 1 %	≤ 1 %	≤ 1 %
Dosimetric system linearity	≤ 1 %	≤ 1 %	≤ 1 %
Dose rate (applicator Ø 10 cm)	10 - 30 Gy/min	3 - 20 Gy/min	According to applicator From 6 to 39 Gy/min
Stray X-radiation (PDD Bremsstrahlung tail)	≤ 0.4 %	≤ 0.7 %	≤ 0.2 %

Source Surface Distance (SSD)	64.5 cm	71.3 cm	65-80 cm
Uniformity or Field Flatness (value at the maximum energy bevel angle 0°)	≤ 3 % Ø 8, 7, 6 [cm] ≤ 7% Ø 10 [cm] (60601-2-1 conformity) ≤ 9 % Ø 4, 5 [cm] ≤ 12 % Ø 3, 12 [cm] ≤ 4 % Ø 9 [cm]	≤ 3 % Ø 10, 8, 7, 6 [cm] ≤ 9 % Ø 4, 5 [cm] ≤ 12 % Ø 3 [cm]	≤ 5 %
COMPONENTS -Mobile Unit			
length	210 cm	210 cm	230 cm
Width	76 cm	76 cm	95 cm
height	180 cm	180 cm	199 cm
weight	570+ (< 230, shield) kg	400+ (< 230, shield) kg	630 kg
Focusing & Collimation	Linac + applicators	Linac + applicators	Linac + applicators
COMPONENTS -Control unit			
Control unit dimensions	80 cm x 60 cm x 120 cm (width, depth, height)	80 cm x 57 cm x 114 cm (width, depth, height)	
Control unit weight	120 kg	100 kg	
COMPONENTS -Applicator			
Applicator length	40 cm	60 cm	100 cm
Applicator size	Ø: 3, 4, 5, 6, 7, 8, 9, 10 and 12 cm each with bevel angels of 0°, 15°, 30°, 45°	Ø: 3, 4, 5, 6, 7, 8, 10 cm each with bevel angels of 0°, 15°, 30°, 45°	Ø: 3, 4, 5, 6, 7, 8, 10 cm
Applicator Material	PMMA	PMMA	PMMA