Sit Sordina Iort Technologies Spa
% Maurizio Pantaleoni
CEO
Isemed Srl
Via P. Togliatti, 19/X
Imola, BO 40026
ITALY

May 22, 2019

Re: K182374
Trade/Device Name: LIAC S
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: Class II
Product Code: IYE
Dated: April 8, 2019
Received: April 11, 2019

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. 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 and Part 809); 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,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

# IV - STATEMENT of INDICATIONS FOR USE

Indications for Use Statement of the LIAC S manufactured by SIT SORDINA IORT TECHNOLOGIES SPA device is provided on the next page.

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)*

K182374

Device Name
LIAC S

Indications for Use *(Describe)*

LIAC S is mobile electron linear accelerator 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 S is 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. The device is not for use by the general public or over-the-counter.
LIAC S is an electron accelerator that can work in an operating theatre 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.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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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 :** SIT SORDINA IORT TECHNOLOGIES SPA
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Owner/Operator Number: 10043521

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**Summary Prepared Date:** August 28, 2018

## 2. Names

| | |
|---|---|
| Device Name: | LIAC S |
| Common Name: | Radiosurgery/radiotherapy treatment planning and delivery system |
| Regulation Name: | Medical charged particle radiation therapy system |
| Product Code: | IYE |
| Classification: | 21CFR 892.5050; Class II |

## 3. Predicate Device

The LIAC S is substantially equivalent to the following predicate device, which is legally marketed in the US.

| Applicant | Device name | 510(k) Number |
|---|---|---|
| SIT SORDINA IORT TECHNOLOGIES SPA. | LIAC HWL | K172961 |

LIAC S and its predicate device LIAC HWL (K172961) are both electron linear accelerators used for radiation therapy during surgical procedures in an operating room and they are both Class II devices.

LIAC S and the predicate LIAC HWL, at the same time, are both regulated under the regulation number 892.5050 and product code IYE.

LIAC S has the same intended use of the predicate device LIAC HWL (K172961). Both devices are electron accelerators that produce beams of electrons used in the radiation therapy treatment of both malignant and benign conditions.
The identified intended use is the radiation therapy treatment of both malignant and benign conditions, during surgical procedures. This technique is also known as "Intraoperative Radiation Therapy (IORT)" and it allows delivery of high doses of radiation directly to tumours or other sites while protecting surgically mobilized normal tissues against dosage impact.

LIAC S and its predicate LIAC HWL are equivalent devices. The only design differences between LIAC S and LIAC HWL are:

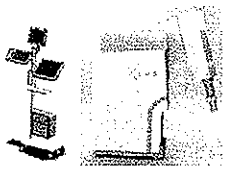
1. Radiation performance parameters
    a) Dose Rate
    b) The surface dose
    c) Stray X-radiation
    d) Surface Surface Distance (SSD)
    e) Uniformity or Field Flatness

2. Mobile and Control Unit mechanical design

3. Components - Applicator
    a) Applicator length

The differences listed above resulted not relevant for the device safety and effectiveness because, as stated into the comparison discussion, they are substantially equivalent to the predicate device LIAC HWL.
All the characteristics and/or performances have been validated with the same methods (i.e. standard compliance) used for the predicate device.
Thus, LIAC S is substantially equivalent to the predicate device LIAC HWL (K172961).

The differences between LIAC S and the predicate device are summarized in the following comparison table:

| **Characteristic** | **PROPOSE DEVICE** | **PREDICATE DEVICE** |
|---|---|---|
| **Device Name** | LIAC S<br>(12mev) | LIAC HWL<br>(Model: 12mev) |
| |  |  |
| | - | K172961 |
| **Manufacturer** | S.I.T. –<br>SORDINA IORT TECHNOLOGIES SPA | S.I.T. –<br>SORDINA IORT TECHNOLOGIES SPA |
| Classification | II | II |
| **Device Design – Technical features** | | |
| Design structure | • Stand (irradiating unit)<br>• Control unit<br>• Applicators | • Stand (irradiating unit)<br>• Control unit<br>• Applicators |
| Emission | Electron beam | Electron beam |
| Type of structure | LINAC | LINAC |
| Docking | Hard docking | Hard docking |
| Remote control | Yes | Yes |
| Nominal energies | 6, 8 ,10, 12 MeV (12 MeV) | 6 ,8 ,10 ,12 MeV (12 MeV) |
| Maximum operating temperature | 25°C | 25°C |
| Electrical power requirement | 230 V, 50 Hz, 3 kVA | 230 V, 50 Hz, 3 kVA |
| Applied Standards | • IEC 60601-1<br>• IEC 60601-1-2<br>• IEC 60601-2-1<br>• IEC 62304 | • IEC 60601-1<br>• IEC 60601-1-2<br>• IEC 60601-2-1<br>• IEC 62304 |
| **Device Design – Radiation performance** | | |
| Surface dose | ≥ 85% | ≥ 90 % (12 MeV) |
| Field symmetry | ≤ 3 % | ≤ 3 % |
| Pulse repetition frequency | 5 - 50 Hz | 5 - 50 Hz (depended on the selected energy) |
| Beam current | 1.5 mA | ≤ 1.5 mA |
| Long term stability | ≤ 3 % | ≤ 3 % |
| Short term stability | ≤ 1 % | ≤ 1 % |

| | | |
|---|---|---|
| Dosimetric system linearity | ≤ 1 % | ≤ 1 % |
| Dose rate (applicator Ø 10 cm) | 2 ÷ 20 Gy/min | 10 - 30 Gy/min |
| Stray X-radiation (PDD Bremsstrahlung tail) | ≤0.7% | ≤ 0.4 % |
| Source Surface Distance (SSD) | 60 cm | 64.5 cm |
| Uniformity or Field Flatness (value in conformity with 60601-2-1 at the maximum energy bevel angle 0° for applicator Ø 10 cm ) | ≤ 5% | ≤ 7% |
| **COMPONENTS -Mobile Unit** | | |
| **Mobile Unit movement capability** | | |
| Translation | 2 degrees of movement | 2 freedom degrees |
| Roll | 1 degree of movement | 1 freedom degree |
| Pitch | 1 degree of movement | 1 freedom degree |
| Elevation | 1 degree of movement | 1 freedom degree |
| **Mobile Unit velocity** | | |
| Hard docking velocity | Up to 0.01 m/s | 0.1 m/s |
| **Mobile Unit size and weight** | | |
| length | 185 cm | 210 cm |
| Width | 76 cm | 76 cm |
| height | 180 cm | 180 cm |
| weight | <550 Kg | 570+ (< 230, shield) kg |
| Focusing & Collimation | Linac + applicators | Linac + applicators |
| **COMPONENTS -Control unit** | | |
| Control unit dimensions | 30 cm x 80 cm x 170 cm (length, width, height) | 80 cm x 60 cm x 120 cm (width, depth, height) |
| Control unit weight | < 50 Kg | 120 kg |
| **COMPONENTS -Applicator** | | |

| | | |
|---|---|---|
| Applicator length | 50 cm (total length) | 40 cm |
| Applicator size | Ø: 3,4,5,6,7,8 and 10 cm each with cutting angles of 0°, 15°, 30°, 45° | Ø: 3, 4, 5, 6, 7, 8, 9, 10 and 12 cm each with bevel angels of 0°, 15°, 30°, 45° |
| Applicator Material | PMMA | PMMA |

After comparing predicate device LIAC S to LIAC HWL, the results show that devices have the same intended use and equivalent technological features, thus they are equivalent in terms of safety and effectiveness.

**5. Device Description**

LIAC S is an electron linear Accelerator used to perform radiation therapy during surgical procedures in an operating room on a patient from whom the Surgeon has just removed a tumor. This technique is known as Intra-Operative Radiation Therapy (IORT) and 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.
The available version of LIAC S is the 12 MeV one, with selectable energies of 6, 8, 10, 12 MeV and with electrical power requirement of 230 V, 50 Hz and 3kVA.

| MODEL | REF. | Version | ENERGY ISSUED |
|---|---|---|---|
| LIAC S | S100000-01-03 | LIAC S (12 MeV) | 6-8-10-12 MeV |

LIAC S model employs the same technology as its predicate, LIAC HWL, with the following differences:

1. The Control Unit frame;
2. The total length of the applicator;
3. The design of the remote controller.

All the differences have no impact on the product performances.
The Equipment, LIAC S, is a system for Intraoperative Radiotherapy comprised of two main parts, Control and Mobile Unit, and the applicators.
The main parts, connected by a ten meters-long cable which transfers the signals and the power are:

1) MOBILE UNIT (STAND). The Mobile Unit is a mobile component which emits the radiation. It is placed in the operating room near the patient with a remote-control device;

2) CONTROL UNIT. The Control Unit is a mobile component too. It is connected to the mobile unit through a group of cables. It is the part of the device that controls the equipment.

Both the above listed components, the mobile unit (1) and the control unit (2), are joined by a cable of about 10 meters, to allow positioning the mobile unit in the operating theatre close to the patient, while the console control unit remains outside of the operating theatre allowing the operator to control the radiation.
The equipment can perform its action only if the Mobile Unit and the Control Unit are connected adequately and the applicator is installed.

### 6. Indications for Use

LIAC S is a mobile electron linear accelerator for intra-operative radiotherapy (IORT). Known as intraoperative radiation therapy (IORT), this technique allows delivery of high doses of radiation directly aimed at tumours or other sites.
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The device 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 S is an electron accelerator that can work in an operating theatre respecting its specific characteristics in terms of cleaning possibility, noise and heat dissipation; in particular, they do not require to move the patient.

### 7. Non-Clinical Performance Testing

Non-clinical testing was conducted for the LIAC S during product development. The modifications described in this Premarket Notification were supported with verification and validation testing. SIT S.p.A claims conformance to the following standards:

- *IEC 60601-1 Medical Electrical Equipment Part.1: General requirements for safety. 1: Collateral standard: safety requirements for Medical Electrical Systems.*
- *IEC 60601-1-2 Medical Electrical Equipment Part.1: General requirements for safety. 2 Collateral standard: electromagnetic compatibility – requirements and tests.*
- *IEC 60601-2-1 Medical electrical equipment -- Part 2-1: Particular requirements for the safety of electron accelerators in the range of 1 MeV to 50 MeV.*
- *ISO 14971 Medical Devices - Application of risk management to medical devices.*
- *IEC EN 62304 Medical device software - Software life cycle processes.*

Evidence provided within this submission demonstrates the compliance of the LIAC S with the applicable standards.

Furthermore, S.I.T. – SORDINA IORT TECHNOLOGIES S.p.A, has also considered the guidance document "*Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices – FDA – May 2005*".

**8. Conclusions**

After comparison of LIAC S to LIAC HWL (K172961), results show that all devices have the same intended use, the same operating principle (linear acceleration) and equivalent technical characteristics. In light of above considerations LIAC S may be considered substantially equivalent to the predicate device.