Panacea Medical Technologies Pvt Ltd.
℅ Valli G.
Plot No. 35, 4th Phase, Malur KIADB Industrial Area
Malur, Kolar District 563130
INDIA

June 8, 2023

Re: K222762
Trade/Device Name: SIDDHARTH-II; IMPACT
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: Class II
Product Code: IYE
Dated: May 4, 2023
Received: May 9, 2023

Dear Valli G.:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Lora D. Weidner -S

Digitally signed by Lora D. Weidner -S
Date: 2023.06.08 16:14:57 -04'00'

Lora D. Weidner, Ph.D.
Assistant Director
Radiation Therapy Team
DHT8C: Division of Radiological Imaging and Radiation Therapy Devices
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222762

Device Name

SIDDHARTH-II and IMPACT

Indications for Use *(Describe)*

SIDDHARTH-II is intended to perform image guided stereotactic radiotherapy for the lesions, tumors & conditions anywhere in the body where radiation treatment is indicated for adults and Pediatric patients.

Integrated Radiation Field Analyser (RFA) of Siddharth-II is intended to collect beam data in water under the aspect of machine QA for the following purposes:
- acceptance testing , periodic QA procedures, and/or commissioning of a radiation therapy system.
- beam data analysis according to international therapy dosimetry protocols
- acquisition, formatting and transfer of basic data to treatment planning systems

The indication for use of Immobilization & Patient Positioning devices (IMPACT) is to immobilize the patient during treatment by providing appropriate support and comfort which in turn leads to precise treatment delivery.

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

K222762

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR §807.92.

I. Submitter's Information

Company Name: Panacea Medical Technologies Pvt Ltd

Company Address: Plot No.35, 4th Phase, Malur KIADB Industrial Area, Malur-563130, Kolar District, INDIA

Contact Name: Ms. Valli

Contact Number : +91 9343779160

Date prepared: 10-Sep-22

III. Device Information

Name of the Device: SIDDHARTH-II;IMPACT

Proprietary Name: Panacea Medical technologies Pvt. Ltd

Common Name: Linear accelerator for radiation therapy system

Classification Name: Medical charged-particle radiation therapy system

Regulatory Class: Class II

Product Code: IYE

IV. Predicate Device

Panacea Device: SIDDHARTH-II	
Legally Marketed Proposed Predicate Device Name	Primary Predicate Device SIDDHARTH-II;IMPACT
Trade/Proprietary Name	Panacea Medical Technologies Pvt. Ltd
510(k) Number	K210894
Date Cleared	28-Sep-21

510(k) Summary

Device Classification:	Class II
Product Code:	IYE

Panacea Device: SIDDHARTH-II	
Legally Marketed reference Device Name	Reference device Dose View 3D
Trade/Proprietary Name	Standard Imaging
510(k) Number	K103193
Date Cleared	27-Dec-2010
Device Classification:	Class II
Product Code:	IYE

V. Device Description

SIDDHARTH-II

SIDDHARTH-II, the subject device remains same as the most recently cleared predicate device SIDDHARTH-II (K210894). In addition, with the features and specifications of existing 510k cleared equipment, the Radiation Field analyzer (RFA) has been permanently integrated with gantry of Siddharth-II to perform beam data analysis as per international therapy dosimetry protocols.

The integrated RFA is retracted and accommodated within the gantry of the radiation therapy equipment after performing data dosimetry operations. This provides an integrated solution for validating the performance of a radiation therapy equipment using an RFA which is in-built with

the radiation therapy equipment that is primarily employed for providing radiation treatments to patients.

The following functionalities can be achieved by using this RFA integrated with Siddharth-II.

- Acceptance testing, Commissioning and Periodic Quality Assurance Measurements for radiation beams emitted by radiation therapy equipment SIDDHARTH-II
- Beam data analysis according to international therapy dosimetry protocols
- Collection of beam data for Treatment Planning System

The RFA setup consists of RFA electromechanical arm for 3-dimensional movement of radiation detector, Ion Chamber (Radiation Detector), Built-in Electrometer, RFA water tank and Water Reservoir. The design control procedures applied to the development of the SIDDHARTH-II and its modifications include requirements reviews, risk analysis, and verification and validation testing. The results of verification and validation activities demonstrate that the acceptance criteria have been met.

All other features and technological characteristics of the SIDDHARTH-II remains as cleared by K210894.

Comparison of Technological Characteristics with the predicate Device

Compared with the predicate device SIDDHARTH-II (K210894), the basic operation and technological characteristics are the same. Operational differences are described in the Instructions for use of SIDDHARTH-II.

Significant differences between the modified device to the existing 510k cleared device appears below.

510(k) Summary

SPECIFICATION	CLEARED DEVICE (SIDDHARTH-II_K210894)	MODIFIED DEVICE (SIDDHARTH-II)
Intended Use	SIDDHARTH-II is intended to perform image guided stereotactic radiotherapy for the lesions, tumors & conditions anywhere in the body where radiation treatment is indicated for adults and Pediatric patients.	Unchanged
Indication for use	SIDDHARTH-II is intended to perform image guided stereotactic radiotherapy for the lesions, tumors & conditions anywhere in the body where radiation treatment is indicated for adults and Pediatric patients. The indication for use of Immobilization & Patient Positioning devices (IMPACT) is to immobilize the patient during treatment by providing appropriate support and comfort which in turn leads to precise treatment delivery.	SIDDHARTH-II is intended to perform image guided stereotactic radiotherapy for the lesions, tumors & conditions anywhere in the body where radiation treatment is indicated for adults and Pediatric patients. Integrated Radiation Field Analyzer (RFA) of Siddharth-II is intended to collect beam data in water under the aspect of machine QA for the following purposes: - acceptance testing, periodic QA procedures, and/or commissioning of a radiation therapy system. - beam data analysis according to international therapy dosimetry

510(k) Summary

SPECIFICATION	CLEARED DEVICE (SIDDHARTH-II_K210894)	MODIFIED DEVICE (SIDDHARTH-II)
		protocols - acquisition, formatting and transfer of basic data to treatment planning systems The indication for use of Immobilization & Patient Positioning devices (IMPACT) is to immobilize the patient during treatment by providing appropriate support and comfort which in turn leads to precise treatment delivery.
User Interface Device	Control Console PC	Unchanged
Use Environment	Hospital (Shielded bunker)	Unchanged
Target to Axis Distance (TAD) (in cm)	100	Unchanged
Gantry range of Rotation (°)	±185	Unchanged
Beam Stopping Devices	Yes	Unchanged
Type of Gantry	Ring	Unchanged
Beam Energy	6 MV	Unchanged

510(k) Summary

SPECIFICATION	CLEARED DEVICE (SIDDHARTH-II_K210894)	MODIFIED DEVICE (SIDDHARTH-II)
Patient Support System	• Lateral • Longitudinal • Vertical • Theta • Pitch • Roll	Unchanged
Treatment Modality	• IGRT With Kv Imaging • 3D CRT Treatment • IMRT Treatment • VMAT Treatment • SBRT Treatment	Unchanged
In-built Automated QA Tool - Radiation Field Analyzer (RFA)	No	Yes
RFA arm Motions (To perform 3-dimensional radiation dose measurements)	No	• Offset Motion (X) • Linear Motion (Y) • Vertical Motion (Z)
Software	SIDDHARTH-II provides an intuitive and simplified workflow for the user to enter, plan, edit and execute patient treatment swiftly through treatment module.	In addition with treatment module, RFA Dosimetry Module has been integrated in SIDDHARTH-II Software to control RFA motions & to perform RFA QA Applications

Indications for Use

510(k) Summary

SIDDHARTH-II is intended to perform image guided stereotactic radiotherapy for the lesions, tumors & conditions anywhere in the body where radiation treatment is indicated for adults and Pediatric patients.

Integrated Radiation Field Analyzer (RFA) of Siddharth-II is intended to collect beam data in water under the aspect of machine QA for the following purposes:

- acceptance testing, periodic QA procedures, and/or commissioning of a radiation therapy system.
- beam data analysis according to international therapy dosimetry protocols
- acquisition, formatting, and transfer of basic data to treatment planning systems

The indication for use of Immobilization & Patient Positioning devices (IMPACT) is to immobilize the patient during treatment by providing appropriate support and comfort which in turn leads to precise treatment delivery.

VI. Substantial equivalence summary

Panacea claims the modified device in this 510k submission to be substantially equivalent to the predicate devices previously cleared by the FDA in the 510(k) specified above.

Panacea claims this equivalence because the proposed devices have equivalent designs, intended uses, target population, patient positioning and used materials. The integration and performance of the new Radiation Field Analyzer for QA purposes was supported by the reference device. Although small technological differences exist, these products have similar product characteristics for use in radiotherapy and further detailed information is included in Substantial Equivalence Discussion of this submission.

VII. Performance Data

Hardware and software verification and validation testing was conducted according to the FDA Quality System Regulation (21 CFR §820), ISO 13485 quality Management System standard, ISO 14971 Risk Management Standard and the other FDA recognized consensus standards listed below. Test results showed conformance to applicable requirements specifications.

The non-clinical data support the safety of the device as compared to the predicate and the software verification and validation demonstrate that the subject device with additional RFA feature performs as intended. Panacea therefore considers the SIDDHARTH-II to be as safe and effective and to perform at least as well as the predicate devices. The imaging, radiation therapy capabilities of the subject device remain same with the existing 510k cleared device.

Software verification testing was conducted as required by FDA's Guidance for Industry and FDA Staff, "Guidance for the content of Premarket Submissions for Software contained in Medical Devices" as it concludes that the software of the subject device was considered as a "Major" level of concern and also it is in compliance with IEC 62304 Software Life cycle processes.

Electrical safety & electromagnetic (EMC) testing were conducted on the SIDDHARTH-II which verified complies with the IEC/ES 60601-1 standards for safety & IEC 60601-1-2 EMC standard.

Non-clinical performance testing for RFA feature of subject device was performed according to IEC 60731:2016 and to specific properties of Ion chamber (Radiation detector), Electrometer, and water phantom systems which included radiotherapy dose measurements i.e. with step by step measurements and also measurement accuracy with respect to radiation detector, positioning, reproducibility and mechanical alignment.

Standards Conformance

SIDDHARTH-II conforms with the FDA recognized standards and other international standards listed below.

ANSI/AAMI ES60601-1, IEC 60601-1-3, IEC 60601-2-1, IEC 60601-2-68, IEC 60601-1-6, IEC 60601-1-2, IEC 62274, IEC 61217, IEC 62304, ISO 10993-1, ISO 10993-5, ISO 10993-10, IEC 60825-1, IEC 60976, IEC 60731, ISO 15223-1, and ISO 14971

VIII. Clinical Testing

Similar devices have been on the market for many years with proven safety and efficacy for the use of the device. Based on this history and the use of the device, clinical testing was not

necessary to support substantial equivalence data. The non-clinical testing performed supports safety and efficacy of the devices in comparison to the predicate and provides data to show substantial equivalence to the predicated device.

IX. Conclusion

The results of verification, validation & safety standards testing demonstrates that the modified SIDDHARTH-II complies to the specified safety & performance criteria & it is substantially equivalent to the predicate device which do not raise any new issues on safety & effectiveness.