Panacea Medical Technologies Pvt. Ltd.
% Ms. Valli
Director
Plot No.35, 4th Phase, Malur KIADB Industrial Area,
Malur-563130, Kolar District
Malur, Kolar District, Karnataka 563130
INDIA

September 28, 2021

Re: K210894
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: June 25, 2021
Received: July 23, 2021

Dear Ms. Valli:

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,

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

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)*
K210894

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.

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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Section 008: 510(k) Summary

K210894

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

II. Applicant Contact Information

Contact Name: Ms. Valli

Contact Number: +91 9343779160

Date prepared: 25-Jun-21

III. Device Information

Name of the Device: SIDDHARTH-II

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

Name of the Device: IMPACT

Proprietary Name: Panacea Medical technologies Pvt. Ltd

Common Name: Immobilization & Patient Positioning Devices

Type:
-Head & Neck Positioning System
-Breast & Thorax Positioning System
-Pelvic & Lower Extremities Positioning System
-One for All Positioning System
-SBRT System – Meticule
-Thermoplastic Immobilization System
-SRS System - Mastereo

Classification Name: Medical charged-particle radiation therapy system

Section 008: 510(k) Summary

Regulatory Class: Class II

Product Code: IYE

IV. Predicate Device

Panacea Device: SIDDHARTH-II		
Legally Marketed Proposed Predicate Device Name	Primary Predicate Device	Secondary Predicate Device
	Halcyon	True Beam
Trade/Proprietary Name	Varian Medical Systems	
510(k) Number	Halcyon: K181032	True Beam: K171733
Date Cleared	Halcyon: 9-May-18	True Beam: 12-Jul-17
Device Classification:	Class II	
Product Code:	IYE	

Panacea Device	**IMPACT Head and Neck Positioning System**			
	Predicate Device	**Predicate Manufacturer**	**Predicate 510(K) number**	**Date Cleared**
IMPACT Head Base Plate	ExaFix-5	Macromedics	K142420	27-Mar-2015
IMPACT Tilting Head Base Plate	Exatilt	Macromedics	K142420	
IMPACT Headrest	Max Support	Macromedics	K142420	

Section 008: 510(k) Summary

Panacea Device	IMPACT Breast & Thorax Positioning System			
	Predicate Device	Predicate Manufacturer	510(K) number	Date Cleared
IMPACT Breast Board	Breast Board LX	Macromedics	K142420	27-Mar-2015
IMPACT Wing Board	Thorax Support	Macromedics	K142420	

Panacea Device	IMPACT Pelvic and Lower extremities Positioning System			
	Predicate Device	Predicate Manufacturer	510(K) number	Date Cleared
IMPACT Hip Fix Base Plate	Pelvic Board	Macromedics	K142420	27-Mar-2015
IMPACT Belly Board	Pelvic Board	Macromedics	K142420	
IMPACT Sigma Pelvic Board	Pelvic Board	Macromedics	K142420	

Panacea Device	IMPACT One for All Positioning System			
	Predicate Device	Predicate Manufacturer	510(K) number	Date Cleared
IMPACT Sigma Board	All in One (AIO) Solution	Orfit	K191158	6-Aug-2019

Panacea Device	IMPACT SBRT System - Meticule			
	Predicate Device	Predicate Manufacturer	510(K) number	Date Cleared
SBRT System - Meticule	Body Pro Lok	Civco Medical Solutions	K153026	25-May-2016

Panacea Device	IMPACT Thermoplastic Immobilization System			
	Predicate Device	**Predicate Manufacturer**	**510(K) number**	**Date Cleared**
IMPACT Thermoplastic Mask	Thermoplastics various sizes & profiles	Macromedics	K142420	27-Mar-2015

Panacea Device	IMPACT SRS System - Mastereo			
	Predicate Device	**Predicate Manufacturer**	**510(K) number**	**Date Cleared**
IMPACT SRS System - Mastereo	NANOR Hybrid Thermoplastic Materials	Orfit	K131795	26-Sep-13

V. Device Description

SIDDHARTH-II

SIDDHARTH-II is an external beam radiotherapy equipment using a linear accelerator with the treatment modalities such as 3D-Coventional radiotherapy, Intensity modulated radiotherapy, Volumetric modulated Arc therapy & Stereotactic body radiotherapy by delivering 6 MV photons with Flattening Filter & Free Flattening Filter.

The Intended Use is achieved under the supervision of the qualified personnel in a shielded room with a patient support system and a control console outside the treatment room. These treatment modalities are delivered with Image Guided Radiation technique using on-board orthogonal kV imaging for generating CBCT and stereotactic images.

SIDDHARTH-II provides an intuitive and simplified workflow for the user to enter, plan, edit and execute patient treatment swiftly. Software functionalities such as patient schedule and patient

alignment has been taken care by frontend software & acquiring volumetric imaging is performed by implementing IGRT technology.

Image processing functionalities such as 3D reconstruction and Image registration by calculating couch shift corrections are performed by Online R&V Software (Image Processing) to ensure patient positioning for accurate treatment which is the supporting software for SIDDHARTH-II frontend software.

In order to fulfill the Intended use and to enhance functionality of SIDDHARTH-II, some of the accessories are integrated along with the system as listed below.

a) Closed Circuit Television System (CCTV)
b) Mike and Speaker
c) Virtual Isocenter Laser
d) Immobilization & Patient Positioning devices (IMPACT)

Indications 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.

Comparison of Technological Characteristics with the predicate Device

SIDDHARTH-II – Linear Accelerator for radiotherapy is substantially equivalent to the predicate device Varian- Halcyon & True Beam which are designed specifically to perform an external beam radiotherapy. They tend to deliver the energies in compatible ranges and dose rates are formulated as per International standards with extensive Image Guided Radiotherapy technology using IGRT kV imaging by generating CBCT images which helps in achieving accurate patient positioning for treatment.

The technological similarities in comparison with predicate device as stated below,

- Intended to deliver precision radiotherapy for lesions, tumors and conditions anywhere in the body.
- System comprises of the design features such as Ring type gantry, use of magnetron as RF source with S-Band standing waveguide to deliver compatible energy of 6MV photons.

- Capability of delivering the treatment modalities such as 3D-CRT, SBRT, IMRT, VMAT which are performed with IGRT kV Imaging to ensure accurate patient positioning.

Below following main differences exist between the subject and predicate device.

- Inclusion of rotational movements such as Theta, Pitch and Roll in subject device to deliver precise treatment without affecting the Organs at risk.
- Provided only IGRT kV imaging in subject device to capture images for an accurate patient positioning.

IMPACT

IMPACT Head base plate is designed to deliver firm support & comfortable positioning for patient's head, neck, and shoulder. Tilting Head Base Plate is designed to provide perfect angulation from 5° to 25° with 5° increments. A standard indexing bar is present which helps in fixing the base plate on couch top.

Head rests made up of Carbon Fibre with six different dimensions (A-F) headrest which provides support to the head & neck region & maintains the maximum reproducibility in every treatment.

Prone head support is intended to deliver the best patient positioning in prone position of head & neck during the treatment. This is indexable on Tilting base plate, head & shoulder base plate which provides an accurate treatment delivery.

Breast board is designed to provide complete, reproducible support for the patients by creating perfect angle required while treatment is in breast region. Breast board can be placed on couch top featured with different tilting angulations to the upper body parts & comfortable armrests with rigid locking mechanism, head support can be placed into the baseplate and ergonomic and rigid body stopper is made available for patient comfort & support.

Wing Board is designed for easy positioning, precise repositioning & high patient comfort during breast & thorax treatments in supine position. Wing board are placed on couch top by using standard indexing bar which comfortably positions and supports the arms when the patient is in supine position. Wing board does not have tilting possibility.

Hip Fix base plate is a comprehensive system which facilitates consistent positioning of hip & pelvic regions by affixing the hip fix base pate on couch top by using standard indexing bar. It has

an ergonomic central aperture enabling comfortable supine positioning to patient during the entire screening & treatment.

Belly Board is intended to provide the comfortable positioning for the bowel region when patient is in prone position during the treatment. Lower part of the board supports legs and there are 2 different cushions for resting forehead.

Sigma Pelvic Board is intended to provide a comfortable prone positioning for the patients getting treatment in pelvic and abdomen region. The base plate is light weight, indexable on any couch top and comfortable for the patient.

IMPACT Sigma board System is designed to position the patient for delivering "One for All" treatments to provide support & exact positioning of the patient for all body parts which can fix & detach the sigma board on couch top based on need for base plates.

Thermoplastic immobilization is intended to immobilize patient to increase precision during treatment delivery. These thermoplastic masks are non-sticky, perforated, smooth & durable. The uniform perforation & uniform thickness of these masks are ideal to customise on patient's anatomy to reproduce in the next fraction of treatment.

SBRT System is intended for limiting the patient motion (intrafraction motion) during treatment, to ensure patient is close to the intended treatment site thus avoiding errors, and to hold patient close to the original simulation geometry. It is intended to use for immobilizing the patient for lungs and moving organ treatments. This system consists of couch top made of carbon fibre, bridge rail, Indexing bar, Wing Board, Head Rest, Bridge with Respiratory Plate or Respiratory belt. The patient set-up is similar to all the boards like supine position with the arms mainly positioned above the patient's head. Knees, and feet positioned in indexed positions. The mechanical pressure system consists of a bridge with a respiratory plate. Abdominal compression can also be created with respiratory belt which is inflatable.

IMPACT SRS System immobilizes the patient by confining the head and provide corrective tilting of the head for treatment and simulation.

IMPACT SRS system consists of couch top, Head Base plate, Head Rest and SRS mask.

These SRS thermoplastic masks are non-sticky, perforated, smooth & durable. The uniform perforation & uniform thickness of these masks are ideal to customise on patient's anatomy to reproduce in the next fraction of treatment.

Indication for Use

The indication for use of Immobilization and 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.

Comparison of technological Characteristics:

IMPACT Head & Neck positioning system is substantially equivalent to the Macromedic's predicate device, which are designed to provide comfort positioning for patient's head, neck and shoulder which helps in achieving accurate treatment delivery. The design of both the devices are equivalent in shape, construction materials and functionality. Both the predicate and the IMPACT Head Base plate are made up of Carbon Fibre which is of similar material and can be placed on top of couch for head, neck, and shoulder positioning.

Both the predicate and the IMPACT Head Rest are made up of carbon fibre which is of similar material. The biological safety evaluation has supported the claim of safety when used in contact the patient's skin.

IMPACT Breast & Thorax Positioning System is substantially equivalent to Macromedic's predicate device, which are designed to position the breast and thorax area of a patient. The design of both the devices are equivalent in shape, construction materials and functionality. Both the predicate and the Breast & Thorax Positioning System are made up of Carbon Fibre which is of similar material and can be placed on top of couch for breast & thorax positioning.

Pelvic & Lower Extremities Positioning System is substantially equivalent to predicate device, which are designed to position the hip, pelvic, abdomen, lower extremity region of a patient. The design of both the devices are equivalent in shape, construction materials and functionality. Both the predicate and the Pelvic and Lower Extremities positioning system are made up of Carbon Fibre which is of similar material and can be placed on top of couch for patient positioning.

Sigma Board is substantially equivalent to predicate device All in One (AIO) Solution - Orfit, which are designed to exact positioning of the patient for all the body parts. The design of both the devices are equivalent in shape, construction materials and functionality. Both the predicate and the IMPACT Sigma Board are made up of carbon fibre which is of similar material and can be placed on top of couch for positioning.

IMPACT thermoplastic mask is substantially equivalent to predicate device Thermoplastic Positioning System- Macromedics which are used to retain and reproduce a patient's position during radiation therapy. The design of both the devices are equivalent in shape, construction materials and functionality. Both the predicate and the IMPACT Thermoplastic & SRS masks are made up of similar thermoplastic material of various sizes & profiles.

IMPACT SBRT System is substantially equivalent to predicate device Body Pro-Lok System for SBRT – Civco Medical Solutions which are used for patient positioning restricting the respiratory movement during radiation therapy. The Respiratory Belt provides pneumatic compression and immobilization to the abdominal region for SBRT treatments. The design of both the devices are equivalent in shape, construction materials and functionality. Both the predicate and the IMPACT SBRT System have one bridge with variable height adjustment.

VI. Substantial equivalence summary

Panacea claims the proposed device in this bundle 510k submission to be substantially equivalent to the 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. 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

Design Verification testing & biocompatibility requirements was performed according to ISO 10993-1 (Biocompatibility Evaluation of medical devices), ISO 10993-5 (Tests for Invitro Cytotoxicity), ISO 10993-10 – (Tests for Irritation & Skin sensitization) and ISO 14971 Risk Management Standard and the other FDA recognized consensus standards.

The imaging and radiation therapy capabilities of SIDDHARTH-II showed substantial equivalence to the predicate device. Testing executed on the system verified conformance to design requirements and ensured all identified risks and hazards were mitigated and demonstrated conformance to relevant safety standards. SIDDHARTH-II described in this premarket notification passed all verification testing, and the system conformed to all applicable section of the standards.

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.

For the IMPACT (Immobilization and Patient Positioning devices) accessory which is a part of ME system, there are no performance standards or special controls have been developed under Section 514 of the Federal Food, Drug, and Cosmetic Act ("FD&C Act"). Bench testing was performed for dosimetry properties that includes attenuation factor and validated to demonstrate SE to the predicate in safety and effectiveness.

The devices are intended for limited contact duration (<24 hours) for surface devices (skin). Biocompatibility testing was completed for patient-contacting materials in accordance with ISO 10993-1, ISO 10993-5 and ISO 10993-10.

VIII. 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, ISO 15223-1, and ISO 14971

In addition to above, the IMPACT accessory also conforms to the following international standards as listed.

ISO 10993-1, ISO 10993-5, ISO 10993-10, ISO 14971

IX. 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 and provides data to show substantial equivalence to the predicate device.

X. Conclusion

The results of verification, validation & safety standards testing demonstrates that SIDDHARTH-II & its IMPACT accessory 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.