May 12, 2025

P-Cure, Ltd.
% Lina Kontos
Regulatory Counsel
Hogan Lovells US LLP
555 Thirteenth Street NW
Washington, District of Columbia 20004

Re: K242418
Trade/Device Name: P-Cure Proton Therapy System (PPTS)
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical Charged-Particle Radiation Therapy System
Regulatory Class: Class II
Product Code: LHN
Dated: September 19, 2024
Received: September 19, 2024

Dear Lina Kontos:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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, 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K242418

Device Name

P-Cure Proton Therapy System (PPTS)

Indications for Use *(Describe)*

The PPTS is a medical device designed to produce and deliver a proton beam for the treatment of patients with localized tumors and other condition susceptible to treatment by radiation.

When the patient is in the seated position using the chair, the System is indicated for treatment of patients with localized tumors and other conditions susceptible to treatment by radiation in the head, neck and thorax.

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.

510(k) SUMMARY

P-Cure, Ltd.'s P-Cure Proton Therapy System (PTTS)

Submitter:

P-Cure, Ltd.
14 Carmel St.
Shilat Industrial Zone, 7318800, Israel
Phone: +972 54 488 1399
Contact Person: Ori Lubin

Date Prepared: May 9, 2025

Name of Device: P-Cure Proton Therapy System (PTTS)

Common or Usual Name: Proton beam therapy systems

Classification Name: Medical Charged-Particle Radiation Therapy System, 21 CFR 892.5050

Regulatory Class: Class II

Product Code: LHN

Predicate Device:

P-Cure Proton Beam Therapy System (PPBTS) (K221996)

Reference Device:

ProTom Radiance 330 (K191521)

Intended Use / Indications for Use:

The PPTS is a medical device designed to produce and deliver a proton beam for the treatment of patients with localized tumors and other condition susceptible to treatment by radiation.

When the patient is in the seated position using the chair, the System is indicated for treatment of patients with localized tumors and other conditions susceptible to treatment by radiation in the head, neck and thorax.

Technological Characteristics:

The P-CURE Proton Therapy System (PPTS) is comprised of four main subsystems that function in tandem to generate the desired dose level and distribution at the target site:

- **Beam production system (Synchrotron based accelerator)**
  - Injector – produces and delivers protons to the synchrotron

- Synchrotron ring – accelerates the proton beam in circular orbit (within the ring) to the desired energy level
- Extraction system - extracts the beam from the ring to the beam delivery subsystem

- **Beam delivery system for a single fixed beam treatment room.** Steers and monitors the extracted proton pencil beam from the synchrotron to the desired treatment location (Nozzle).

- **Patient Positioning System (P-ARTIS).** Mechanically orients the patient (seated or on supine); provides independent means of patient registration using CT (3D) and X-ray (2D)
  - CT system (P-ARTIS CT)
  - Robotic arm and chair/couch (6 Degree of freedom Couch) (P-ARTIS PPS)
  - X-ray system (P-ARTIS XR)
  - Positioning Software (P-ART)

- **Control and Safety Systems**
  - Control Subsystem (TSM). Synchronizes the various subsystem actions and connects with hospital oncology information systems and PACS.
  - Safety Subsystem. Includes hardware and software means to ensure safe system operation for patient and personnel. It includes subsystem interlocks, treatment beam parameters monitoring, and others.

Summary of Technological Characteristics and Comparison to Predicate Device:

The PPTS, the predicate device, and the reference device all share the same fundamental principles of operation, namely that they accelerate a proton beam to the same energy range by using a synchrotron and identically deliver the prescribed treatment dose to the patient by a pencil beam scanning technique. The PPTS uses the same image guided and robotic patient positioning system (P-ARTIS) to move the patient ensuring delivery of the beam to the target area, as prescribed.

While the previously cleared PPBTS positioned patients in a seated position alone, the PPTS can additionally position the patient in a supine position for treatment using an off-the-shelf couch, similar to the identified reference device, ProTom Radiance 330. The PPTS, PPBTS, and ProTom Radiance 330 all use the same robotic arm for mounting the patient support.

In all three systems, the simulation CT dataset are acquired in the treatment patient orientation. For a “seated” planning, the CT dataset is acquired by using in room vertical CT (performed identically for planning for PPBTS and PPTS). For a “supine” planning, the CT simulation data is generated at standard simulation settings of radiation oncology departments (performed identically for planning for ProTom Radiance 330 and PPTS). In all three systems, orthogonal x-ray imaging is used for image guided position verification at isocenter.

A table comparing the key features of the subject, predicate, and reference devices is provided below.

Device Characteristic	P-Cure Proton Therapy System (PPTS)	P-Cure Proton Beam Therapy System (PPBTS) (Predicate Device)	Radiance 330 Proton Beam Therapy System (Reference Device)
510(k) Number	K242418	K221996	K191521
Intended Use/ Indications for Use	The PPTS is a medical device designed to produce and deliver a proton beam for the treatment of patients with localized tumors and other condition susceptible to treatment by radiation. When using the chair, the System is indicated to treatment of patients with localized tumors and other conditions susceptible to treatment by radiation in the head, neck and thorax.	The P-CURE system is a medical device designed to produce and deliver a proton beam for the treatment of patients with localized tumors and other condition susceptible to treatment by radiation in the head, neck and thorax.	The ProTom Radiance 330 is a medical device designed to produce and deliver a proton beam for the treatment of patients with localized tumors and other condition susceptible to treatment by radiation
Accelerator	Synchrotron	Synchrotron	Synchrotron
Particle	Protons	Protons	Protons
Variable	Yes; 70-250 MeV	Yes; 70-250 MeV	Yes; 70-250 MeV
Cycle Time	Variable	Variable	Variable
Beam Transport	Bending and focusing magnets	Bending and focusing magnets	Bending and focusing magnets
Nozzles	Pencil Beam Scanning	Pencil Beam Scanning	Pencil Beam Scanning
Beam Range in Patient (Tissue Depth)	3 cm to 38 cm clinical use	3 cm to 38 cm clinical use	3 cm to 38 cm clinical use
Range Verifier	Optional	Optional	Optional
Control and Safety System	Software controls accelerator, beam transport and delivery, sets operational parameters, monitors systems and provides alerts regarding error conditions.	Software controls accelerator, beam transport and delivery, sets operational parameters, monitors systems and provides alerts regarding error conditions.	Software controls accelerator, beam transport and delivery, sets operational parameters, monitors systems and provides alerts regarding error conditions.
Mechanical Beam Stops	Yes	Yes	Yes
Beam Intensities	Continuously variable over range	Continuously variable over range	Continuously variable over range

Shielding	Steel and Concrete	Steel and Concrete	Steel and Concrete
Gantry Rotating Angle	N/A. Fixed beam	N/A. Fixed beam	Rotating gantry and Fixed beam
Patient Positioner	Yes – couch or chair mounted on a robotic patient positioning device	Yes – chair mounted on a robotic patient positioning device	Yes – couch mounted on a robotic patient positioning device
Patient Positioner	6 degree of freedom robotic positioning device.	6 degree of freedom robotic positioning device.	6 degree of freedom robotic positioning device.
Maximum Load	Chair: 180 kg Couch: 235 kg	Chair: 180 kg	Unknown
Imaging	Yes – Diagnostic quality CT (seated configuration) and orthogonal x-ray system	Yes – Diagnostic quality CT and orthogonal x-ray system	Yes – couch mounted CBCT and x-ray system
Treatment Room	Horizontal fixed gantry with a robotic chair or a couch	Horizontal fixed gantry with a robotic chair	Rotating gantry with a robotic couch Horizontal fixed gantry with a robotic couch

Performance Data:

The Company performed testing as follows:

- Mechanical testing to verify performance of the positioning system
- Beam performance testing to evaluate beam dose shape, beam dose, dose rate, dose monitoring, and spot positioning
- Safety interface testing to verify collision sensors, mechanical interlocks
- Simulation and validation testing to verify integration with oncology information systems
- Validation testing to verify integration with positioning system and treatment planning system
- Testing to support repeatability and reproducibility of patient positioning and immobilization

Product safety and essential performance electrical testing was conducted based upon the following consensus standards: IEC 60601-1, IEC 60601-1-2, IEC TR 60601-4-2, EN 606601-2-44, IEC 60601-1-3, IEC 60601-1-8, IEC 60601-2-54, IEC 60601-1-64, IEC 60601-2-68, IEC 62667, and AAPM TG-224.

Software was documented and validated per FDA's Guidance Document "*Content of Premarket Submissions for Device Software Functions*," and per IEC

In all instances, the PTTS functioned as intended and met its specifications. Testing demonstrated substantial equivalence in terms of performance and safety to the predicate.

Substantial Equivalence Conclusion:

The PPTS has the same intended use and substantially similar indications for use and technological characteristics as the predicate, PPBTS (K221996). The minor differences in indications for use statements and technological characteristics between the PPTS and the predicate device do not raise new or different questions of safety or effectiveness. The completed verification and validation data demonstrate that the device meets its specifications with the commercially available patient positioning configuration, which are comparable to those of the reference device. Thus, the PPTS system can be found substantially equivalent to the predicate.