P-Cure Ltd.
% Jonathan Kahan
Partner
Hogan Lovells US LLP
555 Thirteenth Street, N.W.
WASHINGTON DC 20004

March 20, 2023

Re: K221996
Trade/Device Name: P-Cure Proton Beam Therapy System
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: Class II
Product Code: LHN
Dated: February 16, 2023
Received: February 17, 2023

Dear Jonathan Kahan:

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: 2023.03.20 09:44:39 -04'00'

Lora D. Weidner, Ph.D.
Assistant Director
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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)*
K221996

Device Name
P-Cure Proton Beam Therapy System

Indications for Use *(Describe)*
The P-Cure Proton Therapy 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.

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
P-Cure, Ltd.'s Proton Beam Therapy System

Submitter

P-Cure, Ltd.
14 Carmel St.
Shilat Industrial Zone, 7318800
Israel

Phone: +972 54 488 1399

Contact Person: Ori Lubin
Date Prepared: March 15, 2023

Name of Device:

P-Cure Proton Beam Therapy System

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

ProTom International Holding Corp. Radiance 330 Proton Beam Therapy System (K191521)

Device Description:

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 P-CURE proton beam therapy system comprises 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 seated patient; provides independent means of patient registration using CT (3D) and X-ray (2D)
  - CT system (P-ARTIS CT)
  - Robotic arm and chair (6 Degree of freedom Couch) (P-ARTIS PPS)
  - X-ray system (P-ARTIS XR)
  - Positioning Software (P-ARTIS SW)

- **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.

Intended Use / Indications for Use

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.

Summary of Technological Characteristics and Comparison to the Predicate

The P-Cure proton beam therapy system and its predicate Protom Radiance 330 (K191521) are based on the same technological elements where the system is designed to achieve radiation therapy by accelerating protons for delivery through a nozzle to the patient for the treatment of conditions which are susceptible to radiation. The P-cure system uses a similar synchrotron as utilized by the predicate. Both systems use CT to obtain 3D images for planning and positioning. The P-Cure system delivers a treatment by a fixed beam assembly, and uses a robotic patient positioning system to move the patient to ensure delivery of the beam to the target area whereas the predicate system incorporates a gantry to move the beam in conjunction with a robotic patient positioning system. The P-Cure system positions the patient in a seated position compared to the supine position used with the predicate system. These differences do not raise different questions of safety or efficacy and testing demonstrates substantially equivalent performance compared to the predicate. A table comparing the key features of the subject and predicate devices is provided below.

Device	P-CURE System	Radiance 330 Proton Beam Therapy System
510(k) Number	K221996	K191521

Device	P-CURE System	Radiance 330 Proton Beam Therapy System
Intended Use/ Indications for Use	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
Particle	Protons	Protons
Variable Energy	Yes; 70-250 MeV	Yes; 70-250 MeV
Cycle Time	Variable	Variable
Beam Transport	Bending and focusing magnets	Bending and focusing magnets
Nozzles	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
Range Verifier	Optional	Optional
Control and Safety System	Software controls accelerator, beam transport and delivery, sets operational parameters, monitors systems and provides alerts regarding error	Software controls accelerator, beam transport and delivery, sets operational parameters, monitors systems and provides alerts regarding error conditions.
Mechanical Beam	Yes	Yes
Beam Intensities	Continuously variable over range up to 1E10 protons per cycle time.	Continuously variable over range
Shielding	Steel and Concrete	Steel and Concrete
Gantry rotating	N/A. Fixed beam	Rotating gantry
Patient Positioner	Yes – floor mounted chair	Yes – floor mounted couch
Imaging	Yes – Diagnostic quality CT and x-ray system	Yes – couch mounted CBCT and x-ray system
Treatment Room	Fixed beam orientation and rotating chair	Fixed couch position and rotating gantry

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 600601-1-2, 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.

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

Substantial Equivalence

The P-Cure System is as safe and effective as the ProTom International Holding Corp. Radiance 330 Proton Beam Therapy System (K191521). The P-Cure System has the same intended use and substantially similar indications for use technological characteristics, and principles of operation as its predicate device. The minor differences in the specific indications for use statement and technological differences between the P-Cure System and its predicate devices do not raise different questions of safety or effectiveness. Performance data demonstrate that the P-Cure System is as safe and effective as the Radiance 330 Proton Beam Therapy System. Thus, the P-Cure System is substantially equivalent.