DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 8, 2016

P-Cure Ltd.
% Merav Yarmus, Ph.D.
Senior Clinical & Regulatory Affairs Expert
Biomedical Strategy
155 Bialik St.
Ramat-Gan, 5252346
ISRAEL

Re: K160611
Trade/Device Name: P-ARTIS
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: July 6, 2016
Received: July 11, 2016

Dear Dr. Yarmus:

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. 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); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K160611

Device Name
P-ARTIS

Indications for Use *(Describe)*

The P-ARTIS CT scanner is a Computed Tomography X-Ray System intended to produce images of the body by computer reconstruction of X-ray transmission data taken at different angles and planes. The system may include signal analysis and display equipment, patient and equipment supports, components and accessories. The system is intended for scanning patients while seated.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(K) SUMMARY

510(K) Number K160611

Applicant's Name:

P-Cure Ltd.
12 Abba Hillel Street
Lod, 7129409, Israel
Tel: +972-8-6373030
Fax: +972-8-6373090

Contact Person:

Merav Yarmus, Ph.D.
Biomedical Strategy (2004) Ltd.
10 Ha'ta'as Street
Ramat Gan, 5252346, Israel
Tel: +972-3- 6123281
Fax: +972-3-6123282
Mail: merav@ebms.co.il

Date Prepared: February, 2016
Trade Name: P-ARTIS
Classification Name: Computed Tomography X-ray System
Regulation Number: 892.1750
Product Code: JAK
Device Class: II
Panel: Radiology

Predicate Devices:

- AcQSim-Multislice-CT CT scanner [Philips Medical Systems] cleared under K033357 (regulation: 892.1750, Computed Tomography X-ray System, Class II, Product Code: JAK)
- Somatom Plus 4 with Sliding Gantry Option [Siemens Corp.] cleared under K991600 (regulation: 892.1750, Computed Tomography X-ray System, Class II; Product Code: JAK)

Intended Use / Indication for Use:

The P-ARTIS CT scanner is a Computed Tomography X-Ray System intended to produce images of the body by computer reconstruction of X-ray transmission data taken at different angles and planes. The system may include signal analysis and display

equipment, patient, and equipment supports, components and accessories. The system is intended for scanning patients while seated.

Device Description:
The P-ARTIS CT scanner is an adaptation of the cleared Philips AcQSim-Multislice-CT scanner (K033357, aka Brilliance Big Bore 16 Slice CT scanner) for imaging patients in a seated position. This adaptation is designed by P-Cure in agreement with Philips Medical Systems (Cleveland), Inc. P-Cure has developed a patient Chair and a wall mounted Sliding Platform that is responsible for moving the Gantry up and down along the center axis of the Gantry opening while the patient is seated. The Gantry motion serves to position the scan plane at the start of the region to be scanned and to increment the position of the scan plane during the scan itself.

Being a modification of the cleared Philips AcQSim CT scanner, the principal mode of operation and the essential principles of operation are the same as those of the AcQSim CT scanner. A difference yet exists in the implementation of the scan plane incrementation: instead of moving the table with the lying patient In and Out of the scan plane, the P-ARTIS moves the Gantry scan plane Up and Down over the seated patient. The relative motion is however considered identical between the two systems.

Substantial Equivalence:
The P-ARTIS CT scanner as well as its two predicates, the AcQSim system and the Somatom system, are all CT scanners intended to produce images of the body by computer reconstruction of X-ray transmission data taken at different angles and planes. The adaptation of the P-ARTIS system for scanning seated patients has no effect on its fundamental intended use or indications for use nor does it alter the P-ARTIS diagnostic characteristics or quality attribute as a CT scanner.

The P-ARTIS system is basically its predicate device, the Philips AcQSim system, that has been modified by P-Cure in order to enable imaging patients in a seated position. Consequently, the P-ARTIS system is comprised of hardware (HW) and software (SW) components that are highly similar to those of its AcQSim system predicate. The modifications introduced relate to the configurational changes that apply for scanning a seated patient and they do not change the fundamental control elements and processes. Also, the same key operational procedures and mode of operation apply to both systems and the types of acquired images are shared: Surview, Axial, and Helical. As a result, the essential functionality, capabilities, and output of the P-ARTIS system as a CT scanner are kept as its AcQSim predicate.

Both the P-ARTIS system and its Siemens predicate (*i.e.*, the Somatom system) consist of a moving gantry rather than a moving patient table. The scan control in the Somatom system is designed to move the gantry relative to the table instead of moving the table relative to the gantry. In the P-ARTIS system, a patient chair is included instead of a CT table, and the gantry is movable vertically to the chair. That is, in both the Somatom and the P-ARTIS systems, the gantry movement functions like the movable table in other CT scanners. While the direction of the gantry movement is different as well as the type of patient support (table *vs.* chair), the same fundamental concept of having a movable gantry that moves along a stationary patient support is applied in both systems.

A comprehensive testing program was performed in order to demonstrate the safety and performance of the P-ARTIS CT scanner. The testing program included the following main aspects:

- Electrical safety and electromagnetic compatibility testing, performed in an external laboratory according to AAMI/ANSI ES60601-1 and IEC 60601-1-2 standards.
- Bench testing, performed using phantoms and demonstrated the imaging capabilities and accuracy of the P-ARTIS CT scanner and its comparability to the Philips AcQSim predicate.
- Software verification and validation testing

Tests results indicated that the P-ARTIS CT scanner performs according to its specifications and to the requirements established for a CT scanner.

Conclusion:

P-Cure Ltd. believes that the P-ARTIS CT scanner is as safe and effective as its predicate devices for its intended use and is substantially equivalent to its predicate devices without raising any new safety and/or effectiveness issues.