January 9, 2019

Polymer Technology Systems, Inc. d/b/a PTS Diagnostics
Samuel Engelman
Regulatory Affairs Specialist
7736 Zionsville Road
Indianapolis, IN 46268

Re: K182781
Trade/Device Name: PTS Professional Chemistry Kit
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: CGA, LCP, LBR, CHH, JGY
Dated: September 28, 2018
Received: October 1, 2018

Dear Samuel Engelman:

This letter corrects our substantially equivalent letter of December 21, 2018.

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. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit/tray. 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 and Part 809); 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Kellie B. Kelm -S

for Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
k182781

Device Name
PTS Professional Chemistry Kit

Indications for Use *(Describe)*
The PTS Professional Chemistry Kit is a medical device convenience kit that quantitatively measures the percent of glycated hemoglobin (%Alc), total cholesterol, high density lipoprotein (HDL), triglycerides, and glucose in capillary (fingerstick) or venous whole blood.

• Cholesterol measurements are used in the diagnosis and treatments of disorders involving excess cholesterol in the blood and lipid and lipoprotein metabolism disorders.
• HDL (lipoprotein) measurements are used in the diagnosis and treatment of lipid disorders (such as diabetes mellitus), atherosclerosis, and various liver and renal diseases.
• Triglycerides measurements are used in the diagnosis and treatment of patients with diabetes mellitus, nephrosis, liver obstruction, other diseases involving lipid metabolism or various endocrine disorders.
• Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia, and idiopathic hypoglycemia, and of pancreatic islet cell carcinoma.
• The HbA1C test provides quantitative measurement of the percent of glycated hemoglobin levels. The test is for professional use to monitor glycemic control in people with diabetes.

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.

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K182781 Summary

PTS Professional Chemistry Kit

This summary of safety and effectiveness information is submitted in compliance with 21 CFR 807.92.

Submitted By:

Submission:	Traditional 510(k) Premarket Notification
Applicant:	Polymer Technology Systems, Inc. d/b/a PTS Diagnostics
Contact:	Samuel Engelman
Applicant Address:	Polymer Technology Systems, Inc. 7736 Zionsville Road Indianapolis, IN 46268
Contact Phone:	(317) 870-5610 ext. 1009
Email:	sengelman@ptsdiagnostics.com

Device Information:

Trade Name:	PTS Professional Chemistry Kit
Classification Names:	Cholesterol (Total) Test System (21 CFR 862.1175) Lipoprotein Test System (21 CFR 862.1475) Triglyceride Test System (21 CFR 862.1705) Glucose Test System (21 CFR 862.1345) Glycosylated Hemoglobin Assay (21 CFR 864.7470)
Product Codes:	CHH – Enzymatic Esterase - Oxidase, Cholesterol LBR- Ldl & Vldl Precipitation, Hdl JGY -Colorimetric Method, Triglycerides CGA - Glucose Oxidase, Glucose LCP – Assay, Glycosylated Hemoglobin
Device Class:	II

Predicate Device:

The PTS Professional Chemistry Kit's predicates are manufactured by Polymer Technology Systems, Inc. There are two predicate devices:

1. CardioChek® Plus System (K140068)
2. A1CNow®+ (K090413)

Device Description:

The PTS Professional Chemistry Kit combines devices that are already cleared and packages them together for the convenience of the user.

There are two CardioChek® Analyzers: the CardioChek® PA Analyzer and the CardioChek® Plus Analyzer. These analyzers are part of portable test systems. The CardioChek® PA test system and the CardioChek® Plus test system consist of their respective analyzer and PTS Panels® Test Strips with a lot-specific MEMo® Chip.

The CardioChek® PA and Plus test systems are for the quantitative determination of glucose, total cholesterol, HDL (high density lipoprotein) cholesterol and triglycerides in venous whole blood and capillary whole blood from the fingertip and are intended for multiple patient uses in professional healthcare settings. These systems are for in vitro diagnostic use only.

The PTS Panels® Test Strips consist of varying amounts of test strips packed into a vial and a lot-specific MEMo® Chip. PTS Panels® Test Strips include reflectance and electrochemical test strips. The reflectance assays include quantitative determination of glucose, total cholesterol, HDL (high density lipoprotein) cholesterol and triglycerides. The electrochemical assay is for glucose measurement. The reflectance test strips are available with one, two, and three assays and come in various combinations of assays. The included PTS Panels® Test Strips include: PTS Panels® Lipid Panel Test Strips, PTS Panels® Chol+HDL+Glu Test Strips, PTS Panels® Chol+HDL Test Strips, PTS Panels® Chol+Glu Test Strips, PTS Panels® eGlu Test Strips, PTS Panel® Glucose Test Strips, and CardioChek Plus Smart Bundle™ Pack. The PTS Panels® Test Strips are single-use.

PTS Panels® Controls contain chemicals that react with test strips to produce color or an electrical current depending on the test strips used. Controls should be run to verify the test system performance, when results are questionable, to comply with a facility's quality control requirements, or as required by local accrediting and regulatory bodies. They contain two vials of control solution that have two levels of each analyte. Controls included in this kit are the PTS Panels® HDL Cholesterol Controls and PTS Panels® Multi-Chemistry Controls.

The PTS Collect™ Capillary Tubes are a glass and plastic tube capable of dispensing an exact volume of blood from the capillary tube to a test strip. The tubes are available with volumes of 15, 20, 30, and 40 µL.

The A1CNow®+ test provides quantitative measurement of the percent of glycated hemoglobin (%A1C) levels in capillary (fingerstick) or venous whole blood samples. A1CNow®+ consists of three components: a semi-disposable plastic-encased device (the analyzer), a plastic cartridge enclosing dry reagent strips, and a shaker kit. The units of the analyzer are pre-programmed on the analyzer and are available in either percentage of glycated hemoglobin (%A1C) or millimoles per mole (mmol/mol). The analyzers are lot specific and intended to be discarded once the provided cartridges are consumed.

The Unistik® 3 Pre-set Single Use Safety Lancets are sterile, single-use, auto-disabling lancets to perform finger sticks to obtain capillary blood.

The PTS Connect™ Dock and PTS Connect® ProLink are included to transfer data from the CardioChek® Plus Analyzer, CardioChek® PA Analyzer, and the A1CNow®+ to computer systems. The CardioChek® Printer interfaces with the CardioChek® Plus and CardioChek® PA Analyzer to print results onto paper and self-adhesive labels.

The PTS Professional Chemistry Kit contents are customizable according to user needs. Individual kits may not contain all the devices described in this submission.

Intended Use:

The PTS Professional Chemistry Kit is a medical device convenience kit that quantitatively measures the percent of glycated hemoglobin (%Alc), total cholesterol, high density lipoprotein (HDL), triglycerides, and glucose in capillary (fingerstick) or venous whole blood.

- Cholesterol measurements are used in the diagnosis and treatments of disorders involving excess cholesterol in the blood and lipid and lipoprotein metabolism disorders.
- HDL (lipoprotein) measurements are used in the diagnosis and treatment of lipid disorders (such as diabetes mellitus), atherosclerosis, and various liver and renal diseases.
- Triglycerides measurements are used in the diagnosis and treatment of patients with diabetes mellitus, nephrosis, liver obstruction, other diseases involving lipid metabolism or various endocrine disorders.
- Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia, and idiopathic hypoglycemia, and of pancreatic islet cell carcinoma.
- The HbA1C test provides quantitative measurement of the percent of glycated hemoglobin levels. The test is for professional use to monitor glycemic control in people with diabetes.

Comparison to Predicate:

The PTS Professional Chemistry Kit predicates are comprised of the legally marketed components of the convenience kit. All the provided components in the convenience kit are identical to their legally marketed predicates.

Similarities

Item	Predicates	New Device
Device Name and 510(k) Numbers	CardioChek® Plus System (K140068) A1CNow®+ (K090413)	PTS Professional Chemistry Kit
Intended Use	Quantitatively measures the percent of glycated hemoglobin (%Alc), total cholesterol, high density lipoprotein (HDL), triglycerides, and glucose in whole blood.	Same
Analytes	Total cholesterol, high density lipoprotein (HDL), triglycerides, glucose and glycated hemoglobin	Same

Differences

Item	Predicates	New Device
Device Name and 510(k) Numbers	CardioChek® Plus System (K140068) A1CNow®+ (K090413)	PTS Professional Chemistry Kit
Package	Packaged individually	Packaged as a kit with additional accessories.

Clinical and Non-Clinical Testing

Performance for each device including precision, linearity, limit of detection, analytical specificity and method comparison were established in k140068, k090413, k151545, k162282, k071507, k041750 and k014099.

Conclusion:

The formation of this convenience kit consisting of legally marketed components does not present a significant change to the predicate devices and does not raise new questions of safety and effectiveness as compared to the predicate devices.