510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY AND INSTRUMENT

I Background Information:

A 510(k) Number

K193406

B Applicant

Polymer Technology Systems, Inc. d/b/a PTS Diagnostics

C Proprietary and Established Names

CardioChek Plus and CardioChek Plus Home Test Systems

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
NBW, CGA	Class II	21 CFR 862.1345 Glucose Test System	CH – Clinical Chemistry
CHH	Class I, meets the limitation of exemption 21 CFR 862.9(c)(4)	21 CFR 862.1175 Cholesterol (total) test system	CH – Clinical Chemistry
LBR	Class I, meets the limitation of exemption 21 CFR 862.9(c)(4)	21 CFR 862.1475 Lipoprotein test system	CH – Clinical Chemistry
JGY	Class I, meets the limitation of exemption 21 CFR 862.9(c)(4)	21 CFR 862.1705 Triglyceride test system	CH – Clinical Chemistry

II Submission/Device Overview:

A Purpose for Submission:

Device modifications to previously cleared systems to modify the battery compartment of the meter, modify the analyzer menu display, remove Bluetooth functionality and address software bugs.

B Measurand:

Glucose
Cholesterol (total)
Lipoprotein (HDL)
Triglyceride

C Type of Test:

Quantitative reflectance photometer (cholesterol, lipoprotein, triglyceride)
Quantitative amperometric assay (glucose)

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

The CardioChek Plus Test System

The CardioChek Plus Test System (consisting of the CardioChek Plus analyzer and PTS Panels Chol+Glu test strips) is for the quantitative determination of total cholesterol and glucose in venous whole blood and capillary whole blood from the fingertip and is intended for multiple patient use in professional healthcare settings. This system should only be used with single-use, auto-disabling lancing devices. This system is for in vitro diagnostic use only.

• Cholesterol measurements are used in the diagnosis and treatment of disorders involving excess cholesterol in the blood and lipid and lipoprotein metabolism 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 CardioChek Plus Test System

The CardioChek Plus Test System (consisting of the CardioChek Plus analyzer and PTS Panels Chol+HDL test strips) is for the quantitative determination of total cholesterol and HDL (high density lipoprotein) cholesterol in venous whole blood and capillary whole blood from the fingertip and is intended for multiple patient use in professional healthcare settings. This system should only be used with single-use, auto-disabling lancing devices. This system is for in vitro diagnostic use only.

• Cholesterol measurements are used in the diagnosis and treatment 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.

A Chol/HDL ratio is calculated by the CardioChek Plus analyzer.

The CardioChek Plus Test System

The CardioChek Plus Test System (consisting of the CardioChek Plus analyzer and PTS Panels

Chol+HDL+Glu test strips) is for the quantitative determination of total cholesterol, HDL (high density lipoprotein) cholesterol and glucose in venous whole blood and capillary whole blood from the fingertip and is intended for multiple patient use in professional healthcare settings. This system should only be used with single-use, auto-disabling lancing devices. This system is for in vitro diagnostic use only.

• Cholesterol measurements are used in the diagnosis and treatment 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.

• 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.

A Chol/HDL ratio is calculated by the CardioChek Plus analyzer

The CardioChek Plus Test System

The CardioChek Plus Test System (consisting of the CardioChek Plus analyzer and PTS Panels Lipid Panel test strips) is for the quantitative determination of total cholesterol, HDL (high density lipoprotein) cholesterol and triglycerides in venous whole blood and capillary whole blood from the fingertip and is intended for multiple patient use in professional healthcare settings. This system should only be used with single-use, auto-disabling lancing devices. This system is for in vitro diagnostic use only.

• Cholesterol measurements are used in the diagnosis and treatment 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.

A Chol/HDL ratio and estimated values for LDL (low density lipoprotein) cholesterol are calculated by the CardioChek Plus Analyzer.

The CardioChek Plus Test System

The CardioChek Plus Test System (consisting of the CardioChek Plus analyzer and PTS Panels eGlu test strips) is for the quantitative determination of glucose in venous whole blood and capillary whole blood from the fingertip and is intended for multiple patient use in professional healthcare settings. This system should only be used with single-use, auto-disabling lancing devices. This system is for in vitro diagnostic use only.

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 CardioChek Plus Home Test System

The CardioChek Plus Home Test System (consisting of the CardioChek Plus Home analyzer and CardioChek Plus Home Chol+Glu test strips) is for the quantitative determination of total cholesterol and glucose in capillary whole blood from the fingertip and is intended to be used by a single person and should not be shared. This system is for in vitro diagnostic use only.

• Cholesterol measurements are used in the diagnosis and treatment of disorders involving excess cholesterol in the blood and lipid and lipoprotein metabolism 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 CardioChek Plus Home Test System

The CardioChek Plus Home Test System (consisting of the CardioChek Plus Home analyzer and CardioChek Plus Home Chol+HDL test strips) is for the quantitative determination of total cholesterol and HDL (high density lipoprotein) cholesterol in capillary whole blood from the fingertip and is intended to be used by a single person and should not be shared. This system is for in vitro diagnostic use only.

• Cholesterol measurements are used in the diagnosis and treatment 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.

A Chol/HDL ratio is calculated by the CardioChek Plus Home analyzer

The CardioChek Plus Home Test System

The CardioChek Plus Home Test System (consisting of the CardioChek Plus Home analyzer and CardioChek Plus Home Chol+HDL+Glu test strips) is for the quantitative determination of total cholesterol, HDL (high density lipoprotein) cholesterol and glucose in capillary whole blood from the fingertip and is intended to be used by a single person and should not be shared. This system is for in vitro diagnostic use only.

• Cholesterol measurements are used in the diagnosis and treatment 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.

• 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.

A Chol/HDL ratio is calculated by the CardioChek Plus Home analyzer.

The CardioChek Plus Home Test System

The CardioChek Plus Home Test System (consisting of the CardioChek Plus Home analyzer and CardioChek Plus Home Lipid Panel test strips) is for the quantitative determination of total cholesterol, HDL (high density lipoprotein) cholesterol and triglycerides in capillary whole blood from the fingertip and is intended to be used by a single person and should not be shared. This system is for in vitro diagnostic use only.

• Cholesterol measurements are used in the diagnosis and treatment 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.

A Chol/HDL ratio and estimated values for LDL (low density lipoprotein) cholesterol are calculated by the CardioChek Plus Home Analyzer.

The CardioChek Plus Home Test System

The CardioChek Plus Home Test System (consisting of the CardioChek Plus Home analyzer and CardioChek Plus Home eGlu test strips) is for the quantitative determination of glucose in capillary whole blood from the fingertip and is intended to be used by a single person and should not be shared. This system is for in vitro diagnostic use only.

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.

C Special Conditions for Use Statement(s):

For the CardioChek Plus Test System:

- Prescription Use
- In vitro diagnostic use
- Should not be used to test critically ill patients
- Not recommended to be used with blood samples from patients in shock, patients with severe dehydration, or patients in a hyperosmolar state (with or without ketosis)
- Not for use on patients who are severely hypotensive
- Blood samples preserved with Fluoride or Oxalate should not be used for testing with this system
- This test system should not be used with neonatal or arterial blood samples
- Only auto-disabling, single use lancing devices should be used

For the CardioCheck Plus Home Test System:

- OTC - Over The Counter
- In vitro diagnostic use
- Single-patient use only
- The system is not for use when the patient is critically ill, in shock, severely dehydrated or in a hyperosmolar state
- Not for use on patients who are severely hypotensive
- This device has not been evalutated for the diagnosis of diabetes
- Not for use in screening for diabetes mellitus
- This test system should not be used with neonatal samples

D Special Instrument Requirements:

CardioChek Plus Analyzer
CardioChek Plus Home Analyzer

IV Device/System Characteristics:

A Device Description:

The CardioChek Plus and CardioChek Plus Home Test Systems consist of the analyzer and analyte specific test strips. The CardioChek Test Systems consist of both a reflectance photometer and amperometer. Test strips for measuring cholesterol, lipoprotein (HDL), triglycerides, and glucose by reflectance are available for use with the systems. Additional glucose test strips (eGlu test strips) are available to determine glucose amperometrically. The test strips are packaged in a vial with a MEMo Chip (contains lot specific test strip information) and instructions. The analyzer is provided with analyzer check strips to use as a

check of the electronic and optical components of the analyzer. Certain test strip box configurations may include a single-use only blood lancet (previously cleared under k920562). Quality control materials are available for purchase separately: PTS Panels multi-chemistry controls (Level 1 and Level 2) and PTS Panels HDL cholesterol controls (Level 1 and Level 2).

B Principle of Operation:

The CardioChek analyzers employs both light reflectance and electrochemical biosensor technology to measure an enzymatic chemical reaction. When a blood sample is applied to a reflectance test strip, a chemical reaction occurs that produces a color change on the test strip. When blood is applied to an electrochemical test strip, an electrical current is produced. The resulting color or current is measured and compared to a calibration curve stored in the lot-specific MEMo Chip. The analyzer converts this color or current reading into a test result (the darker the color or greater the electrical current, the higher the analyte concentration) that is displayed on the meter.

C Instrument Description Information:

Modes of Operation	Yes	No
Does the applicant's device contain the ability to transmit data to a computer, webserver, or mobile device?	☒	☐
Does the applicant's device transmit data to a computer, webserver, or mobile device using wireless transmission?	☐	☒
Software		
FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types.	☒	☐

1. Instrument Name:

   CardioChek Plus Analyzer
   CardioChek Plus Home Analyzer

2. Specimen Identification:

   Test results are automatically stored in the CardioChek analyzer's memory. The analyzer can store up to 50 results of each analyte and 10 results for control tests. The analyzer allows review of the results in order from the most recent to the oldest. Each result is displayed with time and date.

3. Specimen Sampling and Handling:

   The CardioChek Plus Test System is intended to be used with venous whole blood and capillary whole blood from the fingertip and the CardioChek Plus Home Test System is intended to be used with capillary whole blood from the fingertip. The whole blood sample is applied directly to the test strip by capillary action.

4. Calibration:

Each package of test strips contains a MEMo Chip that contains lot specific test strip information such as the calibration curve, test strip lot number and the measuring range for each test. The MEMo Chip must be inserted into the meter to run a test with blood or quality control material. The labeling instructs the user to match the lot number code on the test strip vial, MEMo Chip and analyzer.

5. Quality Control:

Liquid quality control materials for use with the systems can be purchased separately: PTS Panels multi-chemistry controls (Level 1 and Level 2) and PTS Panels HDL cholesterol controls (Level 1 and Level 2). Recommendations on when to perform a control test are provided in the labeling. The analyzers have a Control Test setting for the user to select when performing the test so that Control results will be stored in the meter separately from the patient results. The user is cautioned not to use the meter if the control results fall outside the ranges provided on the range card provided with the controls.

Analyzer check strips are provided for use with the analyzers to check that the analyzer's electronic and optical systems are functioning properly. It is recommended that the check strip verification be performed: daily, if the analyzer has been dropped, or if a result is inconsistent with expected results.

V Substantial Equivalence Information:

A Predicate Device Name(s):

Cardiochek Plus Test System, Cardiochek Home Test System

B Predicate 510(k) Number(s):

k140068

C Comparison with Predicate(s):

Device & Predicate Device(s):	K193406	K140068
Device Trade Name	CardioChek Plus and CardioChek Plus Home Test System	CardioChek Plus and CardioChek Plus Home Test System
General Device Characteristic Similarities		
Intended Use/Indications For Use	• Cholesterol measurements are used in the diagnosis and treatment of disorders involving excess cholesterol in the blood and lipid and lipoprotein metabolism disorders.	Same

Device & Predicate Device(s):	K193406	K140068
	• 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.	
Analyte Measurement Technology	Reflectance photometry and amperometry	Same
Specimen Matrix	• CardioChek Plus Test System: Venous whole blood and capillary fingerstick whole blood • CardioChek Plus Home Test System: capillary fingertip whole blood	Same
General Device Characteristic Differences		
Battery Compartment	New design of the battery compartment prevents contact between negative battery terminal and positive terminal, even if batteries are inserted incorrectly	Unmodified battery compartment that could allow the negative terminal of one battery to contact the positive terminal of the other when replacement batteries were installed incorrectly

VI Standards/Guidance Documents Referenced:

None referenced.

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

The CardioChek Plus and CardioChek Plus Home Test Systems consist of the same physical analyzer and test strips. The differences between the systems include the intended use setting (prescription use in professional healthcare settings vs. over-the-counter), the claimed sample types and the names.

1. Precision/Reproducibility:

   See k140068, k151545 and k162282 for the candidate systems and test strips.

2. Linearity:

   See k140068, k151545 and k162282 for the candidate systems and test strips.

3. Analytical Specificity/Interference:

   See k140068, k151545 and k162282 for the candidate systems and test strips.

   The following are included in the labeling for both systems:

   - Acetaminophen (Tylenol) and dopamine may interfere causing the test result to be higher than the actual glucose.
   - Dopamine and methyldopa decreased the results of HDL cholesterol.
   - Extremely high doses of ascorbic acid (Vitamin C) may decrease HDL results. Normal concentrations of Vitamin C did not affect the glucose results.
   - Grossly lipemic samples may interfere with some methodologies.

4. Assay Reportable Range:

   The reportable ranges have not changed. The reportable ranges are listed in the package insert for each test strip as:
   Glucose: 40-600 mg/dL
   Cholesterol (total): 100-400 mg/dL
   Lipoprotein (HDL): 20-120 mg/dL
   Triglyceride: 50-500 mg/dL

5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):

   See k140068, k151545 and k162282 for the candidate systems and test strips.

6. Detection Limit:

   The detection limits have not changed. See section VII.A.4 above for the measuring ranges for each analyte.

7. Assay Cut-Off:

   Not applicable.

8. Accuracy (Instrument):

   Not applicable. See Section VII.B.1 below for method comparison.

9. Carry-Over:

   Not applicable.

B Comparison Studies:

1. Method Comparison with Predicate Device:

   See k140068, k151545 and k162282 for the candidate systems and test strips.

2. Matrix Comparison:

   See k140068, k151545 and k162282 for the CardioChek Plus Test System. Only fingerstick capillary whole blood is used with the CardioChek Plus Home Test System.

C Clinical Studies:

1. Clinical Sensitivity:

   Not applicable.

2. Clinical Specificity:

   Not applicable.

3. Other Clinical Supportive Data (When 1. and 2. Are Not Applicable):

   Not applicable.

D Clinical Cut-Off:

Not applicable.

E Expected Values/Reference Range:

See k140068, k151545 and k162282 for the candidate systems and test strips.

F. Other Supportive Instrument Performance Characteristics Data:

Electrical Safety
The sponsor provided documentation certifying that acceptable electrical safety testing of the analyzer with the modified battery compartment had been performed and the system was found to be compliant.

Thermal Testing
The sponsor conducted thermal testing using the modified battery compartment and batteries inserted incorrectly (reverse/backwards insertion) demonstrating that the modified battery compartment functioned as intended and adequately mitigated the risk of overheating with improper insertion of batteries.

Usability study
The sponsor conducted a usability study using the modified systems with the updated menu display on the analyzer. Participants in the study were representative of the intended users of each system (professional users and lay-users). Results demonstrated that users were able to navigate the menu and perform testing successfully.

Infection control
The CardioChek Plus Test System is intended for multiple-patient use in professional healthcare settings. The CardioChek Plus Home Test System is intended for single-patient use. Disinfection efficacy studies were performed previously (k140068) by an outside commercial testing laboratory demonstrated complete inactivation of duck hepatitis B virus (HBV) with the chosen disinfectant, Super Sani-Cloth (EPA Registration #9480-4). Previous robustness studies (k140068) demonstrated that there was no change in performance, functionality or external materials after 11,001 cleaning and 11,001 disinfection cycles designed to simulate a 3 year use life of the device. Adequate instructions for the validated cleaning and disinfection procedures are provided in the labeling of the device.

VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

IX Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.