February 26, 2022

Polymer Technology Systems, Inc. d/b/a PTS Diagnostics
Margo Enright
Director of Regulatory and Clinical Affairs
4600 Anson Boulevard
Whitestown, Indiana 46075

Re: K193406
Trade/Device Name: CardioChek Plus Test System; CardioChek Plus Home Test System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: NBW, CGA, CHH, LBR, JGY
Dated: October 15, 2020
Received: October 16, 2020

Dear Margo Enright:

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 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/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,

Marianela Perez-Torres, Ph.D.
Deputy Director
Division of Chemistry
and Toxicology Devices
OHT7: Office of In Vitro Diagnostics
and 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K193406

Device Name
CardioChek Plus Test System

Indications for Use *(Describe)*
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.

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)

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Indications for Use

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510(k) Number *(if known)*
K193406

Device Name
CardioChek Plus Test System

Indications for Use *(Describe)*
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.

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)

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K193406

Device Name
CardioChek Plus Test System

Indications for Use *(Describe)*

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.

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)

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K193406

Device Name
CardioChek Plus Test System

Indications for Use *(Describe)*

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.

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)

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K193406

Device Name
CardioChek Plus Test System

Indications for Use *(Describe)*
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.

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)

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510(k) Number *(if known)*
K193406

Device Name
CardioChek Plus Home Test System

Indications for Use *(Describe)*

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.

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)

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510(k) Number *(if known)*
K193406

Device Name
CardioChek Plus Home Test System

Indications for Use *(Describe)*

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

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)

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K193406

Device Name
CardioChek Plus Home Test System

Indications for Use *(Describe)*

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.

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)

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510(k) Number *(if known)*
K193406

Device Name
CardioChek Plus Home Test System

Indications for Use *(Describe)*

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.

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)

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Food and Drug Administration

Indications for Use

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Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K193406

Device Name
CardioChek Plus Home Test System

Indications for Use *(Describe)*

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.

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)

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SECTION 5: 510(k) SUMMARY- k193406

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

January 24, 2022

1. Submitter Information/Facility Address:
Polymer Technology Systems, Inc. d/b/a PTS Diagnostics
4600 Anson Boulevard
Whitestown, IN 46075

2. Contact Person: Margo Enright, RAC
Phone Number: 317-870-5610 x1012
email: menright@ptsdiagnostics.com

3. Trade Names/Models:

- CardioChek Plus Test System
- CardioChek Plus Home Test System

Components:

- CardioChek Plus analyzer
- CardioChek Plus Home analyzer
- 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
- CardioChek Plus Home Lipid Panel test strips
- CardioChek Plus Home Chol+HDL+Glu test strips
- CardioChek Plus Home Chol+HDL test strips
- CardioChek Plus Home Chol+Glu test strips
- CardioChek Plus Home eGlu test strips

4. Regulatory Information

Product Codes: NBW Glucose test system
CGA Glucose test system
CHH Cholesterol (total) test system
LBR Lipoprotein test system
JGY Triglyceride test system

Device Classification: Class II

CardioChek Plus Test System

Product Code	Classification	Regulation Section	Panel
CGA	Class II	21 CFR 862.1345 Glucose test system	Chemistry (75)
CHH	Class I, meets the limitation of exemption 21 CFR 862.9(c)(4)	21 CFR 862.1175 Cholesterol (Total) test system	Chemistry (75)
LBR	Class I, meets the limitation of exemption 21 CFR 862.9(c)(4)	21 CFR 862.1475 Lipoprotein test system	Chemistry (75)
JGY	Class I, meets the limitation of exemption 21 CFR 862.9(c)(4)	21 CFR 862.1705 Triglyceride test system	Chemistry (75)

CardioChek Plus Home Test System

Product Code	Classification	Regulation Section	Panel
NBW CGA	Class II	21 CFR 862.1345 Glucose test system	Chemistry (75)
CHH	Class I, meets the limitation of exemption 21 CFR 862.9(c)(4)	21 CFR 862.1175 Cholesterol (Total) test system	Chemistry (75)
LBR	Class I, meets the limitation of exemption 21 CFR 862.9(c)(4)	21 CFR 862.1475 Lipoprotein test system	Chemistry (75)
JGY	Class I, meets the limitation of exemption 21 CFR 862.9(c)(4)	21 CFR 862.1705 Triglyceride test system	Chemistry (75)

5. Device Description:

- The CardioChek Plus and CardioChek Plus Home analyzers are professional (Rx) use (CardioChek Plus) and home use/OTC (CardioChek Plus Home) *in vitro* diagnostic systems to measure various analytes in capillary fingerstick whole blood for both home and professional use and in venous whole blood for professional use only for glucose, cholesterol, HDL cholesterol, and triglycerides.

- The system includes a small analyzer and test strips. The analyzers utilize PTS Diagnostics brands of dry strip chemistry test strips. The test strips are single-use and utilize one of two types of technologies: reflectance photometry and amperometric/electrochemical technology.

- The test strips are used with the CardioChek Plus and CardioChek Plus Home analyzers to measure total cholesterol, HDL cholesterol, triglycerides, and glucose in whole blood. The test strips utilize enzymatic methods on dry colorimetric test strips that are read by reflectance photometry or amperometric/electrochemical test strips that measure the current produced when blood is applied to the test strip. These test strips are for in vitro diagnostic use only.

- The analyzer has software that converts the reflectance or current produced into an analyte concentration by comparing the reading to a lot-specific calibration curve that is programmed into a EEPROM MEMo chip that is inserted into the analyzer. Each vial of test strips includes a lot-specific MEMo chip, thus eliminating any need for the user to calibrate the system.

- The analyzer is powered by 4 AA alkaline batteries.

6. Intended Uses:

Lipid Panel Professional (Rx)
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.

Chol+Glu+HDL Professional (Rx)
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.

Chol+HDL Professional (Rx)
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.

Chol+Glu Professional (Rx)
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.

eGlu Professional (Rx)
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.

Lipid Panel Home (OTC)
The CardioChek 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 Home Analyzer.

Chol+HDL+Glu Home (OTC)
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.

Chol+HDL Home (OTC)
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.

Chol+Glu Home (OTC)
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.

eGlu Home (OTC)
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.

7. Purpose of Submission

This 510(k) submission is for a modification of the CardioChek Plus Test System and CardioChek Home Test System, originally cleared May 22, 2015, under K140068. The modification for which this 510(k) is being submitted is a modification to the battery compartment of the analyzer case back. The CardioChek Plus/ Home test systems are the same as that described in the 510(k) Summary for K140068 and more recently cleared under K162282.

The modification is a redesign of the battery compartment in the back of the analyzer case. This modification prevents the negative terminal of the battery from contacting the positive terminal of the case when batteries are accidently inserted with the polarity reversed. This user error (reversed polarity) could result in the batteries overheating in the current design if replacement batteries from one manufacturer are incorrectly inserted. The modification prevents any battery overheating.

8. Predicate:

K140068 CardioChek Plus and CardioChek Home Test System

9. Reason for 510(k): Device Modification

The CardioChek Plus and CardioChek Plus Home test systems are modified to include a modification to the battery compartment of the analyzer case back. The modification is a design change that eliminates the potential for battery overheating if batteries are accidently inserted with the polarity reversed (incorrect insertion). Test strips used with these systems have been cleared under twenty-five 510(k)s since 1998, including most recently: K162282 and K151545.

Statement of Substantial Equivalence;

The modified CardioChek Plus and CardioChek Plus Home analyzers and modified CardioChek Plus System and CardioChek Plus Home System are modifications of the same devices as previously cleared and are substantially equivalent.

Predicate Device Information

Predicate Name:	CardioChek Plus/CardioChek Home Test System
Device Company:	Polymer Technology Systems, Inc. d/b/a PTS Diagnostics
510(k) Number:	K140068

This 510(k) submission is for a modification to devices that are FDA cleared under K140068 and the submitter (PTS) is the holder of the predicate 510(k).

The modified devices have the identical Intended Use/Indications for Use as the unmodified.

The fundamental scientific technology is identical.

Modification to the predicate that is the basis for this 510(k):
Design change to the battery compartment in the back of the analyzer case to eliminate the possibility of contact of the negative terminal of the battery with the positive terminal of the analyzer case when batteries are accidently inserted incorrectly.

Comparison of Modified CardioChek Plus/CardioChek Plus Home to the CardioChek Plus/CardioChek Home- Similarities

Description	Subject Device	Predicate Devices (K140068)
Indications for Use	Identical	See K140068
Prescription/over-the-counter use	Identical	Rx and OTC
Technology	Identical	Reflectance photometry and amperometry

Comparison of Modified CardioChek Plus/CardioChek Plus Home to the CardioChek Plus/CardioChek Home- Differences

Description	Subject Device	Predicate Devices (K140068)
Battery compartment of analyzer case	New design prevents contact between negative battery terminal and positive terminal of case. Even if batteries are installed incorrectly, the modification to the battery case prevents any contact between the negative battery terminal and the positive terminal and the battery case, thus preventing the possibility of overheating.	No issues with all AA batteries available when 510(k) cleared in 2015. Battery modification, by one battery manufacturer, made it such that the manufacturer's battery could allow negative terminal of battery to contact the positive terminal of the analyzer case if replacement batteries are installed incorrectly (polarity reversed). This user error (installing batteries incorrectly) could result in overheating.

Testing:
Testing of the modified battery compartment of the case showed that the new design prevented the negative terminal of the battery contacting the positive terminal of the case when batteries are accidently inserted with the polarity reversed. The modification eliminated any potential concerns associated with incorrect insertion of the batteries.

Conclusion:
The modified CardioChek Plus and CardioChek Plus Home test systems are safe and effective devices and substantially equivalent to the predicates.