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

December 22, 2016

POLYMER TECHNOLOGY SYSTEMS, INC. D/B/A PTS DIAGNOSTICS
MARGO ENRIGHT
DIRECTOR OF REGULATORY AND CLINICAL AFFAIRS
7736 ZIONSVILLE ROAD
INDIANAPOLIS IN 46268

Re: k162282
Trade/Device Name: Cardiochek Plus Test System, Cardiochek Home Test System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: II
Product Code: CGA, NBW, CHH, LBR
Dated: August 11, 2016
Received: August 15, 2016

Dear Ms. 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. 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 Parts 801 and 809); 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 regulations (21 CFR Parts 801 and 809), 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,

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: January 31, 2017 *See PRA Statement on last page.*

510(k) Number *(if known)*

K162282

Device Name
CardioChek Home Test System

Indications for Use *(Describe)*

The CardioChek Home Test System (consisting of the CardioChek Home analyzer and CardioChek 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 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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FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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 on last page

510(k) Number *(if known)*

K162282

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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Indications for Use

Form Approved: OMB No. 0910-0120
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510(k) Number *(if known)*

K162282

Device Name
CardioChek Home Test System

Indications for Use *(Describe)*

The CardioChek Home Test System (consisting of the CardioChek Home analyzer and CardioChek 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 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)*

K162282

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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510(k) Number *(if known)*

K162282

Device Name
CardioChek Home Test System

Indications for Use *(Describe)*

The CardioChek Home Test System (consisting of the CardioChek Home analyzer and CardioChek 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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Indications for Use

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Expiration Date: January 31, 2017
See PRA Statement on last page

510(k) Number *(if known)*

K162282

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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FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

SECTION 5: 510(k) SUMMARY- k162282

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

December 9, 2016

1. Submitter Information/Facility Address:
Polymer Technology Systems, Inc.
7736 Zionsville Road
Indianapolis, IN 46268

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

3. Trade Names:
- CardioChek Plus Test System
- CardioChek Home Test System

Components:
- CardioChek Plus analyzer
- CardioChek Home analyzer
- PTS Panels Chol+HDL+Glu test strips
- PTS Panels Chol+HDL test strips
- PTS Panels Chol+Glu test strips
- CardioChek Home Chol+HDL+Glu test strips
- CardioChek Home Chol+HDL test strips
- CardioChek Home Chol+Glu test strips

4. Regulatory Information

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)

CardioChek Plus Home Test System

Product Code	Classification	Regulation Section	Panel
NBW	Class II	21 CFR 862.1345 Glucose test system	Chemistry (75)
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)

5. Device Description:

The PTS Panels Chol+HDL+Glu, Chol+HDL and Chol+Glu test strips and the CardioChek Home Chol+HDL+Glu, Chol+HDL and Chol+Glu test strips are used with the CardioChek Plus and CardioChek Home analyzers to measure total cholesterol, HDL cholesterol and glucose in whole blood. The test strips utilize enzymatic methods on a dry strip that is read by reflectance photometry. These test strips are for in vitro diagnostic use only.

6. Intended Use:

The CardioChek Home Test System (consisting of the CardioChek Home analyzer and CardioChek 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 Home analyzer.

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 Home Test System consisting of the CardioChek Home analyzer and CardioChek 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 Home analyzer.

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 Home Test System (consisting of the CardioChek Home analyzer and CardioChek 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 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.

7. Reason for Special 510(k):
Device Modifications
The CardioChek Plus Test System and the CardioChek Home Test System are modifications of the original devices (cleared in k071507, k071593 and k041750) to include the following:

- Wireless communications capability (professional system)
- Software solutions capability
- Printer connectivity capability
- MEMo chip appearance
- Battery type
- Multiple language software capability
- Wired PC Communication
- Analyzer dimensions

The CardioChek Plus Test System and the CardioChek Home Test System include the PTS Panels test strips for use with the CardioChek Plus analyzer and the CardioChek Home test strips for use with the CardioChek Home analyzer. The test strips are unmodified from K041750, K071507 and K071593.

The three test strips are: Chol+HDL+Glu, Chol+HDL and Chol+Glu. The current trade names for each are:
a. PTS Panels Chol+HDL+Glu test strips
b. PTS Panels Chol+HDL test strips
c. PTS Panels Chol+Glu test strips
d. CardioChek Home Chol+HDL+Glu test strips
e. CardioChek Home Chol+HDL test strips
f. CardioChek Home Chol+Glu test strips

8. Statement of Substantial Equivalence
The CardioChek Plus Test System and CardioChek Home Test System are substantially equivalent to the predicates (k071507, k071593 and k041750).

9. Predicate Device Information
Predicates
Name: PTS Panels Chol+HDL+Glu Test Strips
Device Company: Polymer Technology Systems, Inc. (PTS)
510(k) Number: K071507

Name: PTS Panels Chol+HDL Test Strips
Device Company: Polymer Technology Systems, Inc. (PTS)
510(k) Number: K071593

Name: PTS Panels Chol+Glu Test Strips
Device Company: Polymer Technology Systems, Inc. (PTS)
510(k) Number: K041750

10. Similarities and Differences

Similarities

- Both systems employ reflectance photometry.
- Both systems provide results that correlate to reference methods.
- Both test systems use the same test strips.
- Both systems require a lot specific memory chip for result calculation, which are included in the same package with the test strips

Differences

- The software for the CardioChek Plus and CardioChek Home analyzers have multiple language options.
- The CardioChek Plus and CardioChek Home analyzers provide:
    - Software solutions capability
    - Wired PC communication capability
    - Printer connectivity capability via a USB
    - Wireless communication capability (professional analyzer)
- The MEMo chip appearance is changed to make it more aesthetically pleasing. (The printed circuit board inside is the unmodified.)
- Analyzer outer case is larger.
- The modified analyzers use 4 AA batteries; the BioScanner Plus uses 2 AAA batteries.

11. Verification and Validation Summary

As required by the risk analysis, all verification and validation activities were performed and the results demonstrated that the predetermined acceptance criteria were met.

12. Conclusion

The intended use of the device is unchanged. The CardioChek Plus and CardioChek Home test systems are as safe and effective and perform as well as the predicate devices: k071507, k071593 and k041750.