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.
MARGO ENRIGHT
DIRECTOR OF REGULATORY AND CLINICAL AFFAIRS
7736 ZIONSVILLE ROAD
INDIANAPOLIS IN 46268

Re: k151545
Trade/Device Name: Cardiochek Plus Test System, Cardiochek Home Test System, Cardiochek PA Test System, Cardiochek PA Home Test System
Regulation Number: 21 CFR 862.1175
Regulation Name: Cholesterol (total) test system
Regulatory Class: I, meets the limitation of exemption 21 CFR 862.9(c)(4)
Product Code: CHH, LBR, JGY
Dated: July 27, 2016
Received: July 29, 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)*
k151545

Device Name
CardioChek Home Test System

Indications for Use *(Describe)*

The CardioChek Home Test System (consisting of the CardioChek Home analyzer and CardioChek 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 ration and estimated values for LDL (low density lipoprotein) cholesterol are 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

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)*
k151545

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 ration 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last p

510(k) Number *(if known)*
k151545

Device Name
CardioChek PA Test System

Indications for Use *(Describe)*

The CardioChek PA Test System (consisting of the CardioChek PA 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 ration and estimated values for LDL (low density lipoprotein) cholesterol are calculated by the CardioChek PA 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
Expiration Date: January 31, 2017 *See PRA Statement on last page.*

510(k) Number *(if known)*
k151545

Device Name
CardioChek PA Home Test System

Indications for Use *(Describe)*

The CardioChek PA Home Test System (consisting of the CardioChek PA Home analyzer and CardioChek 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 ration and estimated values for LDL (low density lipoprotein) cholesterol are calculated by the CardioChek PA 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)*

SECTION 5: 510(k) SUMMARY- K151545

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

December 5, 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
This includes:
- CardioChek Plus analyzer
- PTS Panels Lipid Panel test strips

CardioChek Home Test System
This includes:
- CardioChek Home analyzer
- CardioChek Home Lipid Panel test strips

CardioChek PA Test System
This includes:
- CardioChek PA analyzer
- PTS Panels Lipid Panel test strips

CardioChek PA Home Test System
This includes:
- CardioChek PA Home analyzer
- CardioChek Home Lipid Panel test strips

4. Regulatory Information

Product Code	Classification	Regulation Section	Panel
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 PTS Panels Lipid Panel test strips and the CardioChek Home Lipid Panel test strips are used with the CardioChek Plus, CardioChek PA, CardioChek Home and CardioChek PA Home analyzers to measure total cholesterol, HDL cholesterol and triglycerides 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 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 Home Test System** (consisting of the CardioChek Home analyzer and CardioChek 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.

The **CardioChek PA Test System** (consisting of the CardioChek PA 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 PA Analyzer.

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

7. Reason for Traditional 510(k):

Change in the measuring range (dynamic range) for the HDL cholesterol analyte of the Lipid Panel test strips to 20-120 mg/dL (0.52-3.11 mmol/L).

8. STATEMENT OF SUBSTANTIAL EQUIVALENCE:

The Lipid Panel test strips will be marketed as PTS Panels Lipid Panel test strips and CardioChek Home Lipid Panel test strips. They are substantially equivalent to the currently marketed Lipid Panel test strips (predicate).

9. Predicate Device Information:

Predicate
Name: CardioChek Plus Test System and CardioChek Home Test System
Device Company: Polymer Technology Systems, Inc. (PTS)
510(k) Number: K140068

Name: CardioChek Test System
Device Company: Polymer Technology Systems, Inc. (PTS)
510(k) Number: K023558

10. Similarities and Differences (Lipid Panel current and Lipid Panel new):

Similarities

- The test strips are the same test strips currently marketed.
- The test strips are intended for both prescription and OTC use (professional and home use).
- Both test strips require a lot specific memory chip for result calculation, which are included in the same package with the test strips
- The measuring range for the total cholesterol is 100-400 mg/dL
- The measuring range for the triglycerides is 50-500 mg/dL

Difference
The only difference is in the measuring (dynamic) range for the HDL cholesterol. The HDL cholesterol measuring range is changed to 20-120 mg/dL HDL cholesterol. This is accomplished by programming the lot specific memory chip with calibration parameters for the modified range.

11. Summary of Performance Testing:

Accuracy
Results of an accuracy study comparing whole blood HDL cholesterol on PTS Panels/CardioChek Home Lipid Panel test strips on the CardioChek PA/CardioChek PA Home and the CardioChek Plus/CardioChek Home analyzers to the Roche Cobas Integra 400 plus HDL Cholesterol (reference) are summarized below.

Lipid Panel HDL Cholesterol vs. Reference by analyzer

CardioChek Plus Home	CardioChek Plus	CardioChek PA	CardioChek PA Home
n = 80 samples	n = 80 samples	n = 80 samples	n = 80 samples
y = 0.99x+0.55	y = 0.99x+0.55	y = 0.93x+0.98	y = 0.93x+0.98
r = 0.98	r = 0.98	r = 0.98	r = 0.98

Range of samples tested: 21 to 112 mg/dL HDL cholesterol

Precision

HDL Cholesterol (Multiple operators, analyzers, time periods): Using a lot of Lipid Panel test strips with an extended HDL dynamic range, three operators tested three levels of whole blood samples on five analyzers (CardioChek PA/CardioChek PA Home and CardioChek Plus/ CardioChek Home) for HDL cholesterol over three time periods with the results that follow.

CardioChek PA HDL	**Level 1**	**Level 2**	**Level 3**
No. of Observations (n)	80	80	80
Mean (mg/dL)	38.3	62.4	106.0
Std. Deviation (mg/dL)	1.65	2.26	4.2
Coefficient of Variation (%)	4.3	3.6	4.0
CardioChek PA Home HDL	**Level 1**	**Level 2**	**Level 3**
No. of Observations (n)	80	80	80
Mean (mg/dL)	38.3	62.4	106.0
Std. Deviation (mg/dL)	1.65	2.26	4.2
Coefficient of Variation (%)	4.3	3.6	4.0

CardioChek Plus HDL	**Level 1**	**Level 2**	**Level 3**
No. of Observations (n)	80	80	78
Mean (mg/dL)	39.5	63.3	108.3
Std. Deviation (mg/dL)	1.63	2.66	5.24
Coefficient of Variation (%)	4.1	4.2	4.8
CardioChek Home HDL	**Level 1**	**Level 2**	**Level 3**
No. of Observations (n)	80	80	78
Mean (mg/dL)	39.5	63.3	108.3
Std. Deviation (mg/dL)	1.63	2.66	5.24
Coefficient of Variation (%)	4.1	4.2	4.8

12. Conclusion:

The modified measuring range claim for the PTS Panels Lipid Panel test strips/CardioChek Home Lipid Panel test strips for use on the CardioChek Home Test System, CardioChek Plus Test System, CardioChek PA Test System and CardioChek PA Home Test System provides a product that is as safe and effective as the predicate device (CardioChek Plus Test System and CardioChek Home Test System cleared under k140068 and CardioChek Test System cleared under k023358).