



Food and Drug Administration
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Silver Spring, MD 20993-0002

POLYMER TECHNOLOGY SYSTEMS, INC.
MEGAN BURNS
REGULATORY AFFAIRS ASSOCIATE
7736 ZIONSVILLE ROAD
INDIANAPOLIS IN 46268

July 7, 2015

Re: K151530

Trade/Device Name: CardioChek Plus Professional Test System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: II
Product Code: CGA, CHH, JGY, LBR
Dated: June 5, 2015
Received: June 8, 2015

Dear Ms. Megan Burns:

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,


Katherine Serrano -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

Indications for Use

510(k) Number (if known)
K151530

Device Name

CardioChek Plus Test System

Indications for Use (Describe)

The CardioChek Plus Test System is a small portable analyzer and test strip system 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. The tests strips are for the quantitative determination of glucose, total cholesterol, HDL (high density lipoprotein) cholesterol and triglycerides in venous whole blood and capillary whole blood from the fingertip. A Chol/HDL ratio and estimated values for LDL (low density lipoprotein) cholesterol and non-HDL cholesterol are calculated by the CardioChek Plus analyzer.

- 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.
- 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Section 5: 510(k) Summary

1. Applicant Information:

Polymer Technology Systems, Inc.
7736 Zionsville Road
Indianapolis, IN 46268

Contact Person: Megan A. Burns, RAC

Phone: 317-870-5610

Fax: 317-870-5608

2. Date of Preparation:

July 6, 2015

3. Trade Name:

CardioChek Plus Test System

4. Device Description:

The CardioChek Plus Test System includes the CardioChek Plus professional analyzer and analyte-specific test strips (PTS Panels eGLU test strips, PTS Panels Glucose test strips and PTS Panels Lipid Panel test strips). The CardioChek Plus Test System is modified in this submission by the addition of the CardioChek ChekMate strips. CardioChek ChekMate strips are dry strips that mimic the use of the PTS PANELS test strips to check the CardioChek analyzer system optics, calibration and result handling algorithms. ChekMate strips should not be used as a substitute for liquid quality control materials. There is no change to any of the test strips in any of the above named systems.

5. Classification Names:

Glucose Test System

Panel: Clinical Chemistry 75

Product Codes: CGA

Device Classification: Class 2

Regulation: 21 CFR 862.1345

Cholesterol Test System

Panel: Clinical Chemistry 75

Product Codes: CHH

Device Classification: Class I [meets limitation of exemption as per 21 CFR 862.9(c)(4)]

Regulation: 21 CFR 862.1175

Triglyceride Test System

Panel: Clinical Chemistry 75

Product Codes: JGY

Device Classification: Class I [meets limitation of exemption as per 21 CFR 862.9(c)(4)]

Regulation: 21 CFR 862.1705

Lipoprotein Test System

Panel: Clinical Chemistry 75

Product Codes: LBR

Device Classification: Class I [meets limitation of exemption as per 21 CFR 862.9(c)(4)]

Regulation: 21 CFR 862.1475

6. Intended Use

The CardioChek Plus Test System is a small portable analyzer and test strip system 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. The tests strips are for the quantitative determination of glucose, total cholesterol, HDL (high density lipoprotein) cholesterol and triglycerides in venous whole blood and capillary whole blood from the fingertip. A Chol/HDL ratio and estimated values for LDL (low density lipoprotein) cholesterol and non-HDL cholesterol are calculated by the CardioChek Plus analyzer.

- 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.
- 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 510(k):

Device Modification

8. Predicate Device Information

Device Trade Name: CardioChek Plus Test System

Device Company: Polymer Technology Systems, Inc. (PTS)

510(k) number: k140068

Comparison to Predicate:

The modified system is identical to the unmodified system with the exception of the addition of the CardioChek ChekMate strips.

9. Performance Characteristics

The strips for each system are identical to the previously cleared strips. The CardioChek Plus Test System is unmodified compared to the predicate device with the exception of the addition of the CardioChek ChekMate strips.

CardioChek ChekMate Strips Precision:

An Intermediate Precision evaluation was performed over a 20 day period as described in CLSI EP5-A2 *Evaluation of Precision Performance of Quantitative Measurement Methods*. Three lots of ChekMate strips were evaluated on the CardioChek Plus using two (2) analyzers for each lot. Within run, between run, between day and total % CV for all results were less than 3.0%.

CardioChek ChekMate Strips Value Assignment:

Previously reported in k142302

CardioChek ChekMate Strips Stability:

Previously reported in k142302

Real-time Stability:

The study supports an 18 month stability claim.

Re-use Stability:

The study supports the claimed re-use stability of 500 uses for the ChekMate strips.

10. Conclusion:

The performance characteristics above demonstrate that the modification of the above named test system by the addition of the CardioChek ChekMate strips is substantially equivalent to the unmodified system.