SECTION F: 510(k) Summary

K070017

510(k) SUMMARY

This summary of safety and effectiveness information is submitted in compliance with 21CFR807.92.

1. **Application Date:**
   December 29, 2006

JAN 3 1 2007

2. **Applicant Information:**

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

   Contact Person: Margo Enright
   Phone Number: 317-870-5610
   FAX Number: 317-870-5608
   e-mail: menright@cardiochek.com

3. **Trade Name:**
   PTS PANELS Metabolic Chemistry Panel Test Strips

4. **Classification Names:**
   Common Name(s): Glucose Test System, Lipoprotein and cholesterol (high density lipoprotein) test systems, Triglyceride Test System
   Panel: Clinical Chemistry 75
   Product Codes: NBW, NAQ, NGO

5. **Facility Address:**
   7736 Zionsville Road
   Indianapolis, IN 46268

6. **Device Classification:**
   Class 2 (Regulations: 21 CFR 862.1345, 862.1175, 862.1475, 862.1705)

7. **Intended Use:**
   PTS PANELS Metabolic Chemistry Panel Test Strips are intended to be used by medical professionals and individuals in the home to measure glucose, high density lipoprotein cholesterol and triglycerides in fingerstick whole blood. Glucose measurements are used in the management of carbohydrate metabolism disorders. Cholesterol measurements are used in the diagnosis and treatment of disorders involving excess cholesterol in the blood and lipid and lipoprotein metabolism disorders. 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.

8. **Reason for 510(k):**
   Device Modification

9. **Predicate Device Information**
   The predicate devices for determination of substantial equivalence are:
   Name: PTS PANELS Glucose, HDL Cholesterol and Triglycerides Test Strips

Device Company: Polymer Technology Systems, Inc.
510(k) Numbers:
Glucose: K013068
HDL: K060617
Triglycerides: K991894 and K000586

Similarities and Differences between modified device (PTS PANELS Metabolic Chemistry Test Strips) and the Predicate Device (unmodified- PTS PANELS Glucose, HDL Cholesterol and Triglycerides Test Strips)

Similarities Between Predicate and Modified Device

Item	Predicates	Modified Device
Intended Use	Intended to measure glucose, HDL cholesterol and triglycerides in whole blood.	**Same**
Technology	Dry chemistry test strip for use with PTS reflectance photometer.	**Same**
Product Storage	Store with vial tightly capped in a cool dry place at room temperature of 68-86°F.	**Same**
Specimen	Whole blood from fingerstick or venous blood collected in an EDTA or heparin tube.	**Same**
Chemistry Method	Glucose: Colorimetric enzymatic (glucose oxidase) HDL: Colorimetric enzymatic (cholesterol esterase/oxidase) trinder method for cholesterol. Triglycerides: Colorimetric enzymatic (cholesterol esterase/ glycerophosphate oxidase)	**Same**
Calibration Curve	Resides on a read-only memory (EEPROM) chip packaged with the test strips.	**Same**

Differences Between Predicate and Modified Device

Item	Predicates	Modified Device
Number of test strips to obtain results	Three separate test strips	Single test strip with three tests
Time to obtain results	About one minute for each test.	About two minutes for all three test results.

10. Compliance with Special Controls

Does not apply.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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

JAN 31 2007

Re: k070017
Trade/Device Name: PTS Panels Metabolic Chemistry Panel Test Strips
Regulation Number: 21 CFR § 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: NBW, CGA, JGY, LBR, NAQ, NGO
Dated: December 29, 2006
Received: January 03, 2007

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K070017

Device Name: PTS PANELS Metabolic Chemistry Panel Test Strips

PTS PANELS Metabolic Chemistry Panel Test Strips are intended to be used by medical professionals and individuals in the home to measure glucose, high density lipoprotein cholesterol and triglycerides in fingerstick whole blood. Glucose measurements are used in the management of carbohydrate metabolism disorders. Cholesterol measurements are used in the diagnosis and treatment of disorders involving excess cholesterol in the blood and lipid and lipoprotein metabolism disorders. 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.

Prescription Use _X_ AND/OR Over-The-Counter Use _X_
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Carol C Benson

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

K070017