510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
DEVICE ONLY TEMPLATE

A. 510(k) Number:
k040693

B. Purpose for Submission:
New device

C. Analyte:
LDL Cholesterol

D. Type of Test:
Quantitative

E. Applicant:
Polymer Technology Systems, Inc.

F. Proprietary and Established Names:
PTS PANELS LDL Cholesterol Test Strips

G. Regulatory Information:

1. Regulation section:
   21 CFR 862.1475, Lipoprotein Test System
2. Classification:
   Class I, meets the limitations of exemptions 862.9 (c) (9)
3. Product Code:
   MRR
4. Panel:
   75

H. Intended Use:

1. Intended use(s):
   PTS PANELS LDL Cholesterol Test Strips provide a quantitative measurement of LDL (low density lipoprotein) cholesterol in whole blood. Lipoprotein measurements are used in the diagnosis and treatment of lipid disorders (such as diabetes mellitus), atherosclerosis, and various liver and renal diseases. This system is intended for professional use.
2. Indication(s) for use:
   PTS PANELS LDL Cholesterol Test Strips are intended to measure low density lipoprotein. Lipoprotein measurements are used in the diagnosis and treatment of lipid disorders (such as diabetes mellitus), atherosclerosis, and various liver and renal diseases. This system is intended for professional use.

3. Special condition for use statement(s):
   Prescription Use
4. Special instrument Requirements:
   CardioChek brand analyzer

I. Device Description:

PTS PANELS LDL Cholesterol Test Strips are supplied as 25 strips per vial. Each strip contains the following active ingredients: Cholesterol esterase (microorganism), cholesterol oxidase (microorganism), 4-aminoantipyrine, horseradish peroxidase, substituted aniline derivatives, MOPS (3-morpholinopropane sulfonic acid) buffer, MES (2-N-Morpholino ethanesulfonic acid) buffer, surfactants, polyanions, nonionic surfactants, PEG derivatives, modified cyclic sugars, protecting agents and sodium azide (0.05%) as preservative.

J. Substantial Equivalence Information:

1. Predicate device name(s):
   Roche LDL-C-Plus
2. Predicate K number(s):
   k974733
3. Comparison with predicate:

Similarities		
Item	**PTS Panels**	**Roche LDL-C-Plus**
Intended Use	Direct quantitative determination of LDL cholesterol	Same
Principle	Colorimetric enzymatic assay using surfactants as inhibitors of non-LDL	Same
Differences		
Item	**PTS Panels**	**Roche LDL-C-Plus**
Sample type	Whole blood (fingerstick and EDTA and heparinized venous	Serum or heparinized plasma
Form	Dry (test strip)	Wet (liquid)
Instrumentation	Reflectance photometer	Absorbance photometer

K. Standard/Guidance Document Referenced (if applicable):

NCCLS EP6-P, NCCLS EP7-T, NCCLS EP 5-A, National Cholesterol Education Program Adult Treatment Panel III (ATP III)

L. Test Principle:

LDL Cholesterol test results are based on a reading of light reflected off a test strip that has changed color after blood is applied. The intensity of the color is directly proportional to the concentration of LDL cholesterol in the sample. The analyzer converts this into a LDL cholesterol result and displays it. This test, which

selectively measures LDL Cholesterol, is an enzymatic colorimetric test based on the Trinder Method for the determination of cholesterol. In the presence of oxygen, cholesterol is oxidized by cholesterol oxidase to cholesterol-4-en-one and hydrogen peroxide. In the presence of peroxidase, hydrogen peroxide reacts with 4-aminoantipyrine and N,N-di-substituted aniline to form a blue dye.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Within run imprecision: Twenty replicates each of EDTA whole blood with three levels of LDL were tested. The percent coefficient of variation (% CV) was 4.75% at a level of 80 mg/dL, 5.38% at a level of 114 mg/dL, and 4.87% at a level of 152 mg/dL. In addition, a ten day precision study using the NCCLS EP5-A protocol was performed using three levels of control samples. Within run precision % CV was 2.65% at a level of 97 mg/dL, 3.91% at a level of 140 mg/dL, and 4.58% at a level of 171 mg/dL. Total imprecision % CV was 4.16% at a level of 97 mg/dL, 4.24 % at a level of 140 mg/dL, and 5.26% at a level of 171 mg/dL.

b. Linearity/assay reportable range:

The dynamic range of the assay is 50-250 mg/dL. Samples with LDL values below 50 mg/dL are reported as < 50 mg/dL. Samples with LDL values above 250 mg/dL are reported as > 250 mg/dL. Fresh, EDTA whole blood samples with values ranging from 48 mg/dL to 244 mg/dL when run by the Roche method were tested. The PTS LDL results were plotted against the expected LDL (Roche method) with the following regression equation: $y = 0.809 + 13.24$, $r = 0.973$. Recoveries were calculated vs. the expected LDL value. Percent recovery values ranged from 83.5 % to 126.9 % with 103.3% as the average percent recovery.

c. Traceability (controls, calibrators, or method):

A Cholesterol Reference Method Laboratory Network (CRMLN) certified method is used to set lot-specific calibration curves for each lot of the LDL test strips. Each lot of LDL test strips has a calibration curve set with whole blood samples. The calibration curve resides on an EEprom, called a MEMo chip. A lot specific MEMo chip is packaged in each box of LDL test strips.

d. Detection limit:

The PTS LDL test strips read LDL values from 50-250 mg/dL. Samples with LDL values below 50 mg/dL are reported as < 50 mg/dL. Studies performed and described in the *Linearity/assay reportable range* section above demonstrates the performance at 50 mg/dL.

e. Analytical specificity:

Blood samples preserved with fluoride or oxalate should not be used. EDTA and heparin do not interfere with the test. Hematocrit values

above 57 % may incorrectly lower the results. Hematocrit values lower than 35 % may incorrectly increase the result. The labeling contains a statement that the test system should not be used on neonatal blood samples. Ascorbic acid up to 3 mg/dL, acetaminophen up to 20 mg/dL, ibuprofen up to 40 mg/dL, and salicylate up to 50 mg/dL do not interfere. Bilirubin up to 10 mg/dL, hemoglobin up to 500 mg/dL, uric acid up to 20 mg/dL, and triglycerides up to 500 mg/dL do not interfere. HDL cholesterol up to 90 mg/dL does not interfere. Triglycerides above 500 mg/dL may increase the LDL result. HDL cholesterol above 90 mg/dL may increase the LDL result.

f. Assay cut-off:
See expected values below.

2. Comparison studies:
   a. Method comparison with predicate device:
   Fresh fingerstick capillary blood from 128 non-fasting persons was assayed using the PTS LDL test strips. Venous blood was drawn at the same time and run by the predicate method. The range of values for the samples tested was from 53 to 244 mg/dL. The resulting regression statistics were as follows:
   slope = 0.9348
   y intercept = + 9.51
   r = 0.90
   b. Matrix comparison:
   Interference from heparin and EDTA was tested by drawing blood from a person with an LDL level of about 100 mg/dL into three small heparin and three small K_2EDTA anticoagulant tubes. One of each of the heparin and EDTA tubes was reserved. The blood from one of the heparin tubes was transferred into another empty heparin tube of the same size to obtain a 2x heparin concentration. The same procedure was followed for the corresponding EDTA tube. In the same fashion, blood was tested with 4x the usual heparin and EDTA concentrations. The 4x level of EDTA (702 mg/dL) and the 4x level of heparin (57.6 U/mL) showed no interference with the LDL test strips.
3. Clinical studies:
   a. Clinical sensitivity:
   NA
   b. Clinical specificity:
   NA
   c. Other clinical supportive data (when a and b are not applicable):
   NA
4. Clinical cut-off:
   NA

5. Expected values/Reference range:
   The recommended ranges from the National Cholesterol Education Program (NCEP) Adult Treatment Panel III (ATP III) are as follows:

Below 100 mg/dL	Optimal
100 – 129 mg/dL	Near optimal/above optimal
130 – 159 mg/dL	Borderline high
160 – 189 mg/dL	High
190 mg/dL and above	Very high

N. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.