SEP 2 4 2002

K022898

510(k) SUMMARY

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

1. **Application Date:**
   August 29, 2002

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: mme@diabetes-testing.com

3. **Trade Names:**
   PTS PANELS Lipid Panel Test Strips

4. **Description:**
   The Lipid Panel Test Strips are dry phase test strips that are constructed from a plastic strip holder that holds chemically treated membranes. When whole blood is placed on the test strip, the membranes first separate and isolate the red blood cells, allowing the serum/plasma to flow to the reaction membrane and react to produce a color change. The Lipid Panel Test Strips are for *in vitro* diagnostic use with the BioScanner Plus (CardioChek brand) reflectance photometer.

5. **Classification Names:**
   Cholesterol test system
   Lipoprotein test system
   Panel: Clinical Chemistry 75
   Product Codes: CHH, LBR, JGY

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

7. **Device Classification:**
   Class I (Regulation: 21 CFR 862.1475, 862.1175, 862.1705)

8. **Intended Use:**
   The Lipid Panel Test Strips are intended to measure cholesterol, HDL cholesterol and triglycerides in whole blood on a BioScanner Plus (CardioChek brand) analyzer. 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.

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

10. **Predicate Device Information**
The predicate devices for determination of substantial equivalence is:
Name: PTS PANELS Lipid Panel Test Strips
Device Company: Polymer Technology Systems.
510(k) Number: K013173

Similarities and Differences between the Lipid Panel Test Strip as presented in the original Special 510(k) and the Lipid Panel Test Strip that is the subject of this submission:

Similarities

- **The test strip is the same. There are no differences in chemical formulation, processes or design.**
- **The test strip is used on the same unmodified instrument.**
- **The intended use is the same.**

Differences

Performance: The test strips used for the new CLIA Waiver application gave better precision than those used in the original CLIA precision study. The improved precision performance is the basis of this Special 510(k).
This improvement in precision was due to the scale-up of the process to manufacture larger lots of the test strips and the increase in manufacturing experience in producing this product. Once the product was manufactured on a larger scale, the precision (as measured by lot homogeneity) improved. The precision improvement supported changing the homogeneity testing acceptance criteria from 15% to 10% CV.

11. **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

SEP 2 4 2002

Mr. Margo Enright
Manager of Clinical Affairs
Polymer Technology Systems, Inc.
7736 Zionsville Road
Indianapolis, IN 46268

Re: k022898
Trade/Device Name: Lipid Panel Test Strips
Regulation Number: 21 CFR 862.1175
Regulation Name: Cholesterol (total) Test System
Regulatory Class: Class I
Product Code: CHH, LBR, JGY
Dated: August 29, 2002
Received: September 3, 2002

Dear Mr. 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 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 Part 801); 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.

This letter will allow you to begin marketing your device as described in your 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 advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K022898

Device Name: Lipid Panel Test Strips

Indications for Use:

The Lipid Panel Test Strips are intended to measure cholesterol, HDL cholesterol and triglycerides in whole blood on a BioScanner Plus (CardioChek brand) analyzer. The BioScanner Plus (CardioChek brand) analyzer is intended to be used by healthcare professionals to measure blood analytes on a test strip. 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.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K022898

✓ prescription use

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

Concurrence of CDRH, Office of Device Evaluation (ODE)