K02 3558

510(k) SUMMARY

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

1. **Application Date:**
    October 21, 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

    NOV 1 5 2002

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 a 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. Lipid measurements are used in the diagnosis and treatment of lipoprotein metabolism and lipid disorders (such as diabetes mellitus), atherosclerosis, and various liver and renal diseases. This test is designed for use by healthcare professionals and individuals for personal use at home.

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

10. **Predicate Device Information**
The predicate devices for determination of substantial equivalence are:
Name: BioScanner (PTS PANELS) Cholesterol, HDL Cholesterol and Triglycerides Test Strips
Device Company: Polymer Technology Systems, Inc.
510(k) Numbers: K990688, K993377, K000586

Similarities and Differences between PTS Lipid PANELS Test Strips and the Predicate Devices

Similarities

- Both systems are designed for home use (OTC).
- Both systems determine total cholesterol, HDL cholesterol, and triglycerides concentrations in whole blood.
- Both systems use the same method of red blood cell separation. '
- Both systems use the same reaction membranes for blood separation and color development.
- Both systems use a reflectance photometer to convert the intensity of color produced in a colorimetric chemical reaction into total cholesterol, HDL cholesterol, and triglycerides results.
- Both systems contain a lot specific electronically erasable programmable read-only memory (EEPROM) chip in the same package with the strips. The EEPROM chip has the curve information programmed into it based on a multipoint curve that is established for each lot. The user inserts this chip into the meter with each new lot of test strips.

Differences

- The BioScanner (PTS PANELS) Test System Cholesterol (K990688), HDL Cholesterol (K993377) and Triglycerides (K000586) are constructed on three separate test strips.

  The Lipid Panel Test Strips combine cholesterol, HDL and triglycerides on one test strip.

- The Lipid Panel Test Strips may be used on the BioScanner Plus, which is marketed under the CardioChek brand name, instrument, but not on the BioScanner 2000.

  The BioScanner (PTS PANELS) Cholesterol, HDL Cholesterol and Triglycerides Test Strips may be used on both the BioScanner 2000 and the BioScanner Plus (CardioChek brand) instruments.

11. **Compliance with Special Controls**

Does not apply.

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

NOV 1 5 2002

Re: k023558
        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; JGY; LBR
        Dated: October 21, 2002
        Received: October 23, 2002

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 the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may
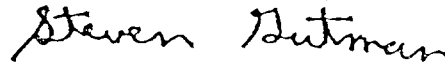publish further announcements concerning your device in the Federal Register.

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" (21 CFR 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 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): _KO23558_

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 test strips are intended to be used by healthcare professionals and individuals at home to measure three blood analytes: cholesterol, HDL cholesterol and triglycerides. 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.

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Division

510(k) Number _K 023558_

RX ___

OTC ___

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

OTC and RX

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