K040693

JUL - 6 2004

SECTION E: 510(k) SUMMARY

This summary of safety and effectiveness information is submitted in compliance with 21CFR 807.92.

March 12, 2004

Submitter 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

Trade Name:
PTS PANELS LDL Cholesterol Test Strips

Common Name: Lipoprotein test system

Panel: Clinical Chemistry 75

Product Code: MRR

Device Classification: Class I

PTS PANELS LDL Cholesterol Test Strips are classified as a Class I device under Clinical Chemistry Systems - Lipoprotein Test System, 21CFR 862.1475.

Predicate Device Information

STATEMENT OF SUBSTANTIAL EQUIVALENCE

Polymer Technology Systems, Inc., intends to introduce into commercial distribution the PTS PANELS LDL Cholesterol Test Strips for the quantitative determination of LDL cholesterol in human whole blood. PTS PANELS LDL Cholesterol Test Strips are substantially equivalent to the predicate device noted below.

Name:	LDL-C Plus
Device Company:	Roche Diagnostics
510(k) Number:	K974733

Similarities and Differences (Predicate and New Device)

Similarities

Item	Predicate- Roche LDL-C Plus (K974733)	New Device- PTS PANELS LDL Cholesterol Test Strip
Intended Use	Direct quantitative determination of LDL Cholesterol	Same
Test Principle	Colorimetric enzymatic assay using surfactants as inhibitors of non-LDL	Same
Sample Requirements	Fasting and non-fasting	Same

Differences

Item	Predicate- Roche LDL-C Plus	New Device- PTS PANELS LDL Cholesterol Test Strip
Sample Type	Serum or Heparinized Plasma	Whole Blood (Fingerstick and EDTA and Heparinized Venous)
Form	Wet (Liquid)	Dry (Test Strip)
Instrumentation Required	Absorbance Photometer	Reflectance Photometer

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUL - 6 2004

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

Re: k040693
Trade/Device Name: PTS PANELS LDL Cholesterol Test Strips
Regulation Number: 21 CFR 862.1475
Regulation Name: Lipoprotein test system
Regulatory Class: Class I
Product Code: MRR
Dated: June 21, 2004
Received: June 22, 2004

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 (301) 594-3084. 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Jean M. Cooper MS, DVM.

Jean M. Cooper, MS, 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): K040693

Device Name: PTS PANELS LDL Cholesterol Test Strips

Indications 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.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(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

510(k) K040693