AUG 2 1 2002

SECTION E: 510(k) Summary

K022401

1. **Application Date:**
   July 19, 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 Multi-Chemistry Controls

4. **Classification Names:**
   Assayed Quality Control Material

   Panel: Clinical Chemistry 75
   Product Code: JJY

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

6. **Device Classification:**
   Class I (Regulation: 21 CFR 862.1660)

7. **Device Description:**
   The PTS PANELS Multi-Chemistry Controls consist of multiple levels of aqueous controls containing cholesterol, triglycerides, ketone (*B*-hydroxybutyrate) and glucose.

8. **Intended Use:**
   The PTS PANELS Multi-Chemistry Controls are intended for use to estimate precision and to detect systematic analytical deviations that may arise from reagent or analytical instrument variation and are intended for use by healthcare professionals in both physicians' offices and in acute and convalescent care facility bedside testing as well as consumers at home.

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

10. Predicate Device Information

The predicate devices for this submission for determination of substantial equivalence are the Maine Standards Validate Chem 1 and Chem 3.

Information on Predicate Devices

New Device	Predicate Device	K Number
PTS PANELS Multi-Chemistry Controls	Maine Standards Validate Chem 1	**K012117**
PTS PANELS Multi-Chemistry Controls	Maine Standards Validate Chem 3	**K012119**

Similarities and Differences Between Predicates and New Device

Items Compared	Similarities	Differences
PTS PANELS Multi-Chemistry Controls and Maine Standards Validate Chem 1.	Both are aqueous. Both contain glucose and triglycerides.	The Maine Standards Validate Chem 1 also contains Na, K, Cl, Ca, PO_4, BUN, Cre, Mg, Lac, NH_3, ETOH and Li. The PTS PANELS Multi-Chemistry Controls also contain cholesterol and ketone (*B*-hydroxybutyrate)
PTS PANELS Multi-Chemistry Controls and Maine Standards Validate Chem 3.	Both contain cholesterol.	The Maine Standards Validate Chem 3 also contains total protein, albumin and Fe. The PTS PANELS Multi-Chemistry Controls also contains glucose, triglycerides and ketone (B-hydroxybutyrate. The Maine Standards Validate Chem 3 is protein based and the PTS PANELS Multi-Chemistry Controls are aqueous.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG 21 2002

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

Re: k022401
Trade/Device Name: PTS Panels Multi-Chemistry Controls
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality control material (assayed and unassayed)
Regulatory Class: Class I
Product Code: JJY
Dated: July 19, 2002
Received: July 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" (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) : K022401

Device Name: **PTS PANELS Multi-Chemistry Controls**

Indications for Use:

The PTS PANELS Multi-Chemistry Controls are intended for use on the BioScanner 2000 and CardioChek brand instruments to estimate precision and to detect systematic analytical deviations that may arise from reagent or analytical instrument variation and are intended for use by healthcare professionals in both physicians' offices and in acute and convalescent care facility bedside testing as well as consumers at home.

Jean Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K022401

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Rx — OTC ✓