SECTION F: 510(k) Summary

K014099

510(k) SUMMARY

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

1. **Application Date:** DEC 21 2001
   December 7, 2001
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:**
   BioScanner Plus
   BioScanner Glucose Test Strips
   BioScanner Beyond Glucose Test Strips
4. **Description**
   The BioScanner Plus, as modified, is an *in vitro* diagnostic device consisting of both a reflectance photometer and an amperometer. This device measures various analytes in blood once the blood is applied to dry phase test strips that are specifically designed for reflectance or amperometric analysis. The test strips have not been modified.

   The unmodified BioScanner Plus contains a reflectance photometer. The modified BioScanner Plus has an additional amperometric circuit.
5. **Classification Names:**
   Glucose Test System
   Panel: Clinical Chemistry 75
   Product Codes: CGA, NBW
6. **Facility Address:**
   7736 Zionsville Road
   Indianapolis, IN 46268
7. **Device Classification:** Class II (Regulation: 21 CFR 862.1345)
8. **Intended Use:**
   The BioScanner Plus Glucose Test Systems are intended for the quantitative determination of glucose in human whole blood for use by healthcare professionals in both physicians' offices and in acute and convalescent care facility bedside testing and individuals at home. Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia, and idiopathic hypoglycemia, and of pancreatic islet cell carcinoma.
9. **Reason for 510(k):**
   Device Modification

10. Predicate Device Information

The following table lists the predicate devices for this submission for determination of substantial equivalence:

New Device	Predicates	K Numbers
Modified BioScanner Plus*	BioScanner Plus*	K013173
	BioScanner 2000*	K972669
	BioScanner Beyond Glucose Analyzer*	K013203

***Device Company:** Polymer Technology Systems

Similarities and Differences

Items Compared	Similarities	Differences
1. Modified BioScanner Plus to BioScanner Plus (K013173)	1. Both include all the same features and technology (reflectance photometry) to run colorimetric tests.	The modified device combines two predicate devices. It combines the amperometric BioScanner Beyond Glucose Analyzer (K013203) with the reflectance photometer in the BioScanner Plus (K013173) and incorporates them into a single device.
2. Modified BioScanner Plus to BioScanner Beyond Glucose Analyzer (K013203)	2. Both include all the same features and technology (to run amperometric tests).	
Test strips used with modified BioScanner Plus		
3. BioScanner Glucose Test Strips (colorimetric test strips:K972669)	3. Same test strip used on modified BioScanner Plus as on BioScanner Plus and BioScanner.	3. None.
4. BioScanner Beyond Glucose Test Strips (amperometric test strips, K013203)	4. Same test strip used on modified BioScanner Plus as on BioScanner Beyond Glucose Analyzer	4. None.
Intended Use: Modified device compared to unmodified.	Same intended use.	None

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 21 2001

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

Re: k014099
Trade/Device Name: BioScanner Plus for Professional and OTC Use
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: NBW
Dated: December 7, 2001
Received: December 13, 2001

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

Center for Devices and Radiological Health

510(k) Number (if known): K014099

Device Name: ~~BioScanner Plus for Professional and OTC Use~~

Indications for Use:

The BioScanner Plus Glucose Test Systems are intended for the quantitative determination of glucose in human whole blood for use by healthcare professionals in both physicians' offices and in acute and convalescent care facility bedside testing and individuals at home. Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia, and idiopathic hypoglycemia, and of pancreatic islet cell carcinoma.

Jean Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K014099

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-CounterUse ✓
(Per 21 CFR 801.109)

(Optional Format 1-2-96)