DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JAN 1 4 2005

Yuji Yagi
ARKRAY, Inc.
57 Nishiaketa-Cho,
Higashi-Kujo, Minami-Ku
Kyoto, Japan 601-8045

Re: k041427
Trade/Device Name: The SpotChem EZ Glucose Test
The SpotChem EZ Fructosamine Test
The SpotChem EZ AST Test
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose Test System
Regulatory Class: Class II
Product Code: CGA, CIS, LCP
Dated: September 27, 2004
Received: October 27, 2004

Dear Yuji Yagi:

This letter corrects our substantially equivalent letter of September 27, 2004 regarding the applicant/ owner which should be listed as Arkray and not Polymedco.

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 (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 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 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 (240)276-0484. 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,

Cornelia B. Rooks

Cornelia B. Rooks, MA
Acting Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Cc: Polymedco, Inc
Helen Landicho, RAC

Indications for Use

510(k) Number (if known): k 041427

Device Name: The SpotChem EZ Glucose Test

Indications For Use:

The SpotChem EZ Glucose test system is an in vitro diagnostic procedure intended to measure glucose quantitatively in human serum and plasma on the SpotChem EZ analyzer.

Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia, and idiopathic glycemia, and of the pancreatic isle cell carcinoma.

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)

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K041427

Indications for Use

510(k) Number (if known): k041427

Device Name: The SpotChem EZ Fructosamine Test

Indications For Use:

The SpotChem EZ Fructosamine test system is an in vitro diagnostic procedure intended to measure fructosamine quantitatively in human serum and plasma on the SpotChem EZ analyzer.

Fructosamine measurements are used to assess the level of control of a patient's diabetes and to determine the proper insulin dosage for a patient. Elevated levels of fructosamine indicate uncontrolled diabetes in a patient.

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)

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K041427

Indications for Use

510(k) Number (if known): k041427

Device Name: The SpotChem EZ AST Test

Indications For Use:

The SpotChem EZ AST test system is an in vitro diagnostic procedure intended to measure AST quantitatively in human serum and plasma on the SpotChem EZ analyzer.

AST mesurements are used in the diagnosis and treatment of certain liver and heart diseases.

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)

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k): k041427