



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Mail Center – WO66-0609  
Silver Spring, MD 20993-0002

Polymedco, Inc.  
c/o Ms. Helen Landicho  
Vice President, Polymedco Regulatory Affairs  
510 Furnace Dock Road  
Cortlandt Manor, NY 10567

OCT 20 2009

Re: k090703  
Trade Name: Poly-Chem 90 Glucose, ALP, and AST tests  
Regulation Number: 21 CFR §862.1345  
Regulation Name: Glucose test system  
Regulatory Class: Class II  
Product Codes: CFR, CJE, CIT  
Dated: September 25, 2009  
Received: October 01, 2009

Dear Ms. Landicho:

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

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If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-5680 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'CCH', with a long horizontal flourish extending to the right.

Courtney C. Harper, Ph.D.  
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): K090703

Device Name: Poly-Chem 90 Glucose, ALP, and AST tests

### Indications For Use:

The Poly-Chem 90 glucose test system is an in vitro diagnostic procedure intended to measure glucose quantitatively in human serum and plasma on the Poly-Chem 90 analyzer. Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia, and idiopathic glycermia, and of the pancreatic isle cell carcinoma.

The Poly-Chem 90 ALP test system is an in vitro diagnostic procedure intended to measure alkaline phosphatase quantitatively in human serum and plasma on the Poly-Chem 90 analyzer. Measurements of alkaline phosphatase are of use in the diagnosis, treatment, and investigation of hepatobiliary disease and in bone disease associated with increased osteoblastic activity. Alkaline phosphatase is also used in the diagnosis of parathyroid and intestinal disease.

The Poly-Chem 90 AST test system is an in vitro diagnostic procedure intended to measure aspartate aminotransferase (AST) quantitatively in human serum and plasma on the Poly-Chem 90 analyzer. AST measurements are used in the diagnosis and treatment of certain types of liver and heart disease.

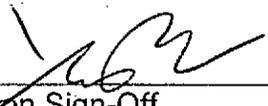
Prescription Use   √    
(Part 21 CFR 801 Subpart D)

AND/OR Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

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

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

  
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Division Sign-Off  
Office of In Vitro Diagnostic Device  
Evaluation and Safety

510(k)   K090703