

Food and Drug Administration 2098 Gaither Road Rockville MD 20850

FFB - 4 2004

Ms. Helen Landicho Director Regulatory Affairs Polymedco, Inc. 510 Furnace Dock Road Cortlandt Manor, NY 10567

Re: k033706

Trade/Device Name: Polymedco Homocysteine Test

Regulation Number: 21 CFR 862.1377

Regulation Name: Urinary homocystine (non-quantitative) test system

Regulatory Class: Class II Product Code: LPS; JIT; JJX Dated: November 25, 2003 Received: November 26, 2003

## 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); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

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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 <a href="http://www.fda.gov/cdrh/dsma/dsmamain.html">http://www.fda.gov/cdrh/dsma/dsmamain.html</a>.

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): <u>033706</u>
Device Name: Polymedco Homocysteine Test .
Indications For Use:
The Polymedco Homocysteine Test is intended for the quantitative in vitro determination of total homocysteine in serum and plasma on automated clinical chemistry analyzers. This device can assist in the diagnosis and treatment of patients suspected of having hyperhomocysteinemia and homocystinuria.
The Homocysteine Calibrators are a device intended for medical purposes for use with the Polymedco Homocysteine assay to establish points of reference that are used in determination of values in the measurement of homocysteine in human serum or plasma.
The Homocysteine Controls are intended for use as an assayed quality control serum to monitor the precision and accuracy of the laboratory testing procedures for total homocysteine.
Note: The parameters and labeling provided are for use on the Polymedco Poly-Chem and the Hitachi chemistry analyzer systems.
Prescription Use AND/OR Over-The-Counter Use (21 CFR 801 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)
Carof C Benson of Jean Cooper, DVM Division Sign-Off
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