

K971113

MAY 29, 1997

Safety and Effectiveness Summary

DMA's Triglyceride (GPO) Procedure is intended for in vitro diagnostic use for the quantitative determination of triglycerides in human serum or plasma. It is quite similar to many other assays which have long been used for this purpose.

DMA's Triglyceride (GPO) Procedure has been shown to have the following performance characteristics.

Linearity	to 1800 mg/dL
Precision	
Within-Run	(Within Normal Range) C.V. of approximately 0.4% (Above Normal Range) C.V. of approximately 0.7%
Run-to-Run	(Within Normal Range) C.V. of approximately 4% (Above Normal Range) C.V. of approximately 1.7%
Shelf-life	14 months (at 2-8°C)
Sensitivity (0.001A)	1.0 mg/dL
Interferences	
Bilirubin	Significant above 4.5 mg/dL
Hemoglobin	Significant above 190 mg/dL
Expected Values	36 - 173 mg/dL



Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 29 1997

C. H. Morris, Ph.D.
• Vice President, Scientific and Government Affairs
- Data Medical Associates, Inc.
845 Avenue G East
Arlington, Texas 76011

Re: K971113
DMA Triglyceride Procedure
Regulatory Class: I
Product Code: CDT
Dated: March 25, 1997
Received: March 27, 1997

Dear Dr. Morris:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Pre-market Approval), 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 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

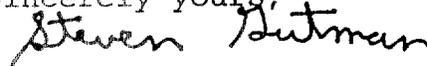
Page 2

Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



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

DMA Triglyceride (GPO) Procedure

510(k) Number (if known): K971113Device Name: Triglyceride, Lipase Hydrolysis/Glycerol Kinase
Enzyme. Trade Name: DMA Triglyceride (GPO) Procedure

Indications for Use: For the quantitative determination of Triglycerides in serum and plasma. Triglyceride measurements are used in the diagnosis and treatment of patients with diabetes mellitus, nephrosis, liver obstruction, other diseases involving lipid metabolism, or various endocrine disorders. Elevated serum triglyceride levels are seen in primary disorders of lipid metabolism or hyperlipoproteinemia secondary to known diseases. Furthermore, in conjunction with high-density lipoprotein and total serum cholesterol, a triglyceride determination provides valuable information for the assessment of coronary heart disease risk. The clinical significance and management of hyperlipoproteinemia depends on the triglyceride distribution among the major serum lipoproteins.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K971113

Prescription Use
(Per 21 CFR 801.109)

or

Over-The-Counter Use