

OCT 8 1999



**DATA MEDICAL ASSOCIATES, INC.**

A subsidiary of Thermo.BioAnalysis Corporation, a Thermo Electron company  
845 AVENUE G EAST  
ARLINGTON, TEXAS 76011-7709 USA

Customer Service & Tech Support 800/558-9115

817/640-0965

FAX 817/649-2461

www.dma-inc.com

### 510 K Summary

This Summary of Safety and Effectiveness is being submitted in accordance with the requirements of SMDA 1990 AND 21 CFR 807.92

Submitter: Data Medical Associates, Incorporated (DMA)

Contact Person: Thomas Dollar, Manager of Regulatory Affairs

The assigned 510(k) number is K993098

Device: HDL Cholesterol and LDL Cholesterol Calibrator  
JIT Secondary Calibrator

Class: II

Predicate Device: HDL Cholesterol and LDL Cholesterol Calibrator, Reference  
Diagnostics Inc, Bedford, MA

Description and Intended Use: DMA's HDL Cholesterol and LDL Cholesterol calibrator is intended for the calibration of in-vitro diagnostic methods for the direct quantitative determination of HDLC and LDLC in serum.

Technological Characteristics: Both DMA and Reference Diagnostics are used for the determination of HDL Cholesterol and LDL Cholesterol in serum.

Date Prepared: 08/31/99



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

OCT 8 1999

Mr. Thomas Dollar  
Manager of Regulatory Affairs  
Data Medical Associates, Inc.  
845 Avenue G East  
Arlington, Texas 76011-7709

Re: K993098  
Trade Name: DMA HDL-C/LDL-C Calibrator  
Regulatory Class: II  
Product Code: JIX  
Dated: September 13, 1999  
Received: September 16, 1999

Dear Mr. Dollar:

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 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). 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 (Premarket 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 Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS 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.

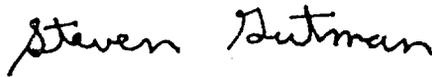
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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/dsma/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



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## INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K993098

Device Name: DMA HDL-C/LDL-C Calibrator

Indications For Use: For the calibration of in-vitro diagnostic methods for the direct quantitative determination of HDL Cholesterol and LDL Cholesterol in serum.

Jean Cooper  
(Division Sign-Off)  
Division of Clinical Laboratory  
510(k) Number K993098

         Rx

         OTC