DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

APR 27 2005

Bola Nicholson MT (ASCP)
Technical Manager
Thermo Electron Corporation
Clinical Chemistry
331 South 104th Street
Louisville, CO 80027

Re: k042767
Trade/Device Name: DataPro™/ DataPro Plus™ Clinical Chemistry Analyzer
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: CFR, CJE, CIX, CIT, CIG, CIC, CGX, CDQ, CEK, CEO, CHH, CDT, CDO,CKA, JJE
Dated: March 4, 2005
Received: March 7, 2005

Dear Ms. Nicholson:

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).

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/industry/support/index.html

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 STATEMENT

510(K) Number K042767

Device Name: DataPro™/DataPro Plus™ Clinical Chemistry Analyzer

Indications for Use:
The DataPro™/DataPro Plus™ Clinical Chemistry Analyzer is a fully automated clinical chemistry analyzer intended for routine diagnostic clinical laboratory use. The DataPro™ has replaceable parts, automated maintenance monitoring and backup of both patient and system data. With a throughput of up to 230 tests per hour, the DataPro™ is intended for small and medium-sized laboratories, or as a backup analyzer in large volume laboratories.

The DataPro™/DataPro Plus™ Clinical Chemistry Analyzer is intended to be used in the diagnosis of disease or other conditions, including a determination of the state of health, in order to cure, mitigate, treat, or prevent disease or its sequelae related to the measurement of various clinical assays, such as Albumin, Alkaline Phosphatase, Alanine Aminotransferase (ALT), Aspartate Aminotransferase (AST), Urea Nitrogen (BUN), Calcium, Cholesterol, Creatinine, Direct Bilirubin, Glucose, Phosphorus, Total Bilirubin, Total Protein, Triglyceride, and Uric Acid.

The DataPro™, and all of the reagents included in this test system are for in vitro diagnostic use only.

Prescription Use √ **OR** **Over-the Counter-Use** _____
(Per 21 CFR 801.109)

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

Carol Benson **concurrence of CDRH, Office of Office of In Vitro Diagnostic Devices (OIVD)**
Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K042767