510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY AND INSTRUMENT COMBINATION TEMPLATE

A. 510(k) Number:
k042767

B. Purpose for Submission:
Thermo Electron Corporation proposes to manufacture and introduce into interstate commerce, for commercial distribution, the Thermo Electron DataPro™ / DataPro Plus™ Clinical Chemistry Analyzer. This is being submitted for use with previously FDA cleared reagents manufactured by Trace and/or DMA, now doing business as Thermo Electron Corporation.

C. Measurand:
Glucose, Alkaline phosphatase, Albumin, Aspartate amino transferase (AST/SGOT), Bilirubin total, Bilirubin direct, Calcium, Creatinine, Urea nitrogen, Total protein, Phosphorus, Cholesterol, Triglyceride, Uric acid, Alanine amino transferase (ALT/SGPT).

D. Type of Test:
Quantitative assays for the DataPro™ / DataPro Plus™ Clinical Chemistry Analyzer

E. Applicant:
Thermo Electron Corporation

F. Proprietary and Established Names:
DataPro™ / DataPro Plus™ Clinical Chemistry Analyzer

G. Regulatory Information:
1. Regulation section:

21 CFR §	862.1345	Glucose test system.
21 CFR §	862.1050	Alkaline phosphatase or isoenzymes test system.
21 CFR §	862.1035	Albumin test system.
21 CFR §	862.1100	Aspartate amino transferase (AST/SGOT) test system.
21 CFR §	862.1110	Bilirubin (total or direct) test system.
21 CFR §	862.1110	Bilirubin (total or direct) test system.
21 CFR §	862.1145	Calcium test system.
21 CFR §	862.1225	Creatinine test system.
21 CFR §	862.1770	Urea nitrogen test system.
21 CFR §	862.1635	Total protein test system.
21 CFR §	862.1580	Phosphorus (inorganic) test system.
21 CFR §	862.1175	Cholesterol (total) test system.
21 CFR §	862.1705	Triglyceride test system.
21 CFR §	862.1775	Uric acid test system.
21 CFR §	862.1030	Alanine amino transferase (ALT/SGPT) test system.
21 CFR §	862.2160	Discrete Photometric Chemistry Analyzer for Clinical Use

2. Classification:
   Class II, Class I (reserved), Class I

3. Product code:

PC	Common Name
CFR	HEXOKINASE, GLUCOSE
CJE	NITROPHENYLPHOSPHATE, ALKALINE PHOSPHATASE OR ISOENZYMES
CIX	BROMCRESOL GREEN DYE-BINDING, ALBUMIN
CIT	NADH OXIDATION/NAD REDUCTION, AST/SGOT
CIG	DIAZO COLORIMETRY, BILIRUBIN
CIC	CRESOLPHTHALEIN COMPLEXONE, CALCIUM
CGX	ALKALINE PICRATE, COLORIMETRY, CREATININE
CDQ	UREASE AND GLUTAMIC DEHYDROGENASE, UREA NITROGEN
CEK	BIURET (COLORIMETRIC), TOTAL PROTEIN
CEO	PHOSPHOMOLYBDATE (COLORIMETRIC), INORGANIC PHOSPHORUS
CHH	ENZYMATIC ESTERASE--OXIDASE, CHOLESTEROL
CDT	LIPASE HYDROLYSIS/GLYCEROL KINASE ENZYME, TRIGLYCERIDES
CDO	ACID, URIC, URICASE (U.V.)
CKA	NADH OXIDATION/NAD REDUCTION, ALT/SGPT
JJE	ANALYZER, CHEMISTRY (PHOTOMETRIC, DISCRETE), FOR CLINICAL USE

4. Panel:
   Chemistry (75)

H. Intended Use:

1. Intended use(s):
   See Indications for use below.

2. Indication(s) 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.

3. Special conditions for use statement(s):
The DataPro™, and all of the reagents included in this test system are for in vitro diagnostic use only.

4. Special instrument requirements:
DataPro™ / DataPro Plus™ Clinical Chemistry Analyzer

I. Device Description:

The DataPro™/DataPro Plus™ (with cuvette washer) is a random access discrete photometric analyzer, capable of performing 48 different tests to 48 samples in a walk-away manner. In Clinical analysis, its purpose is for In Vitro Diagnostics. It performs Laboratory Chemistry Analysis in automated and selective form, either in routine or Stat mode.

The analyzer incorporates robotics, computer and communication technology to render simple and reliable long-term operation. The DataPro™ consists of a system of modules (reagent tray, sampling system and reaction tray) performing specific functions, computer controlled and with bi-directional communication.

Cuvettes are disposable and not for reuse, except where a washer is installed and enabled. Washing occurs automatically after the completion of each run. When the washer is in use, at the beginning of the next run, the system will use the next set of cuvettes after the ones used in the previous run. This prevents over use of the same cuvettes. Precision data were generated using this option at one test site compared to two other sites.

Colors of the cuvettes in the Reaction Tray field are coded as follows:
• Dark Grey: New cuvettes.
• Light Grey: Used, then washed cuvettes (when washer installed).
• Black: The checked absorbance of the empty cuvette is higher than the limit specified in the parameters. It is therefore considered dirty and will not be used. It is washed (where applicable) in the next run. If washing doesn't help, change the cuvette.

For more detailed information see section **O. System Descriptions** below.

J. Substantial Equivalence Information:

1. Predicate device name(s):
Trace America, Inc reagents as follows: Glucose (HK), Alkaline Phosphatase, Albumin Reagent - Bromcresol Green Method, AST Incorporating Dynamic Stabilization Technology (DST), Direct Bilirubin Reagent - Acid Diazo Method, Total/Direct Bilirubin Reagent, Calcium Arsenazo III Reagent, Creatinine Reagent - Picric Acid Method, Urea (Urea Nitrogen) - Incorporating DST, Total Protein Reagent - Biuret Method, Phosphorus Reagent-Direct UV Method,

Cholesterol- Incorporating DST, Enzymatic Triglycerides Reagent, Uric Acid Incorporating DST, and ALT Incorporating DST.

Ciba Corning Diagnostics Corp., Model 550 Express Clinical Chemistry Analyzer

2. Predicate 510(k) number(s):
   k980026, k012518, k870372, k961114, k870365, k911866, k903896, k870366, k971477, k870371, k870368, k962890, k860730, k971485, k961123, k872302 respectively as listed above.

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Reagents	Same	Same
Analyzer • Discrete Photometric Analyzer	Same	Same
• Software Driven	Same	Same
• For clinical laboratory professionals	Same	Same
• Automated dilutions	Same	Same
• Sample reruns	Same	Same

Differences		
Item	Device	Predicate
Reagents Testing Process	Automation on DataPro™ Analyzer	Generic reagent/replacement reagents
Analyzer	DataPro™ Analyzer	550 Express Analyzer

K. Standard/Guidance Document Referenced (if applicable):
All data was collected and statistical analysis for all methods performed according to National Committee of Clinical Laboratory Standards (NCCLS now CLSI) by standards such as:
EP5 - Evaluation of Precision Performance of Clinical Chemistry Devices
EP6 - Evaluation of the Linearity of Quantitative Analytical Methods
EP9 - Method Comparison and Bias Estimation Using Patient Samples

L. Test Principle:
The package insert for each analyte states the test principle.

M. Performance Characteristics (if/when applicable):
1. Analytical performance:
   a. *Precision/Reproducibility:*

Precision was performed per - CLSI Precision Standard, EP5. The results are presented below.

Level	Assay	Mean	Total		With in run	
			SD	CV(%)	SD	CV(%)
I	Glu	93	8.4	9.4	3.5	3.9
II	Glu	300	16.5	5.9	11.4	4.1
I	ALP	95	3.3	3.3	1.9	1.9
II	ALP	483	15.0	3.3	7.2	1.6
I	ALB	3.0	0.12	3.9	0.09	3.0
II	ALB	2.2	0.08	2.1	0.05	2.1
I	AST	29	1.1	3.9	0.8	1.0
II	AST	176	5.6	3.2	1.8	1.0
I	T. Bili	1.1	0.06	5.6	0.04	3.8
II	T. Bili	7.1	0.17	2.4	0.07	1.0
I	D. Bili	0.7	0.10	15.2	0.03	4.6
II	D. Bili	3.3	0.26	8.1	0.06	1.8
I	Ca	8.6	0.22	2.5	0.16	1.9
II	Ca	13.5	0.24	1.9	0.16	1.2
I	Creat	3.0	0.10	3.0	0.08	2.5
II	Creat	6.7	0.20	2.8	0.15	2.1
I	BUN	14	1.0	8.5	0.8	6.6
II	BUN	54	3.4	7.6	2.2	4.9
I	T. Prot	6.9	0.29	4.1	0.19	2.6
II	T .Prot	5.2	0.22	0.22	0.11	2.0
I	Phos	3.6	0.09	2.7	0.07	1.9
II	Phos	6.8	0.32	4.6	0.11	1.6
I	Chol	144	5.1	3.5	3.8	2.6
II	Chol	250	11.4	4.5	6.9	2.7
I	Trig	80	4.6	5.8	3.5	4.4
II	Trig	142	7.8	5.6	5.9	4.2
I	UA	6.2	0.18	3.0	0.09	1.4
II	UA	12.0	0.26	2.3	0.08	0.7
I	ALT	25	1.0	3.9	0.8	3.1
II	ALT	88	3.9	3.9	2.5	2.4

Cuvette Wash Option Precision Study							
Site	Level	Assay	Mean	Total		Between run	
				SD	CV(%)	SD	CV(%)
1	I	T. Prot	4.47	0.28	6.2	0.17	3.8
1	II	T .Prot	3.32	0.21	6.4	0.11	3.4
2	I	T. Prot	4.45	0.11	2.5	0.11	2.5
2	II	T. Prot	3.29	0.10	3.1	0.10	3.1
C/Wash	I	T. Prot	4.41	0.12	2.7	0.12	2.7
C/Wash	II	T. Prot	3.24	0.09	2.9	0.09	2.9

b. *Linearity/assay reportable range:*
   Linearity was performed per - CLSI Linearity Standard, EP6. The results are presented below.

Analyte	N	Slope	Intercept	% Error	Allowable % Error	Range
Glucose	11	1.020	-0.6	2.6	3.0	0 – 788 mg/dL
ALP	6	0.926	4.7	7.1	7.5	10 – 2079 U/L
ALB	6	0.959	0.082	2.1	2.5	0 - 6.71 g/L
AST	5	0.974	0.0	2.6	5.0	7 – 1334 U/L
TBILI	6	1.014	0.03	1.7	5.0	0 - 20.5 mg/dL
DBIL	5	0.987	0.0	2.8	5.0	0 – 20 mg/dL
CAL	5	0.965	-0.013	0.16 mg/dL	0.25 mg/dL	5 – 15 mg/dL
CREA	11	1.000	0.03	3.6	3.8	0 - 26.2 mg/dL
BUN	6	1.007	0.0	3.0	3.6	0 – 128 mg/dL
TPRO	10	0.977	0.1	2.3	2.5	0 - 17.3 g/L
PHOS	5	1.084	-0.1	2.3	2.7	1 – 11 mg/dL
CHOL	11	1.017	0.0	2.7	3	0 - 904.9 mg/dL
TRIG	10	1.018	0.0	2.8	6.3	0 – 1277 mg/dL
UA	5	0.998	-0.23	2.1	4.3	2 – 22 mg/dL
ALT	6	0.993	1.9	4.9	5.0	0 – 545 U/L

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*
   See the package insert for each analyte.

d. *Detection limit:*
   See the package insert for each analyte.

e. *Analytical specificity:*
   See the package insert for each analyte.

f. Assay cut-off:
Not applicable

2. Comparison studies:
   a. *Method comparison with predicate device:*
   The method comparison was performed per – CLSI Method Comparison Standard, EP9. The results are presented below.

Analyte	N	Slope	Intercept	Corr. R	Sample Range
Glucose	60	0.935	-0.2	0.9797	8 – 220 mg/dL
ALP	60	0.94	-4.2	0.9922	40 – 516 U/L
ALB	60	0.9	0.28	0.9254	2.2 – 5.5 g/L
AST	55	0.97	-1.7	0.9732	8 – 90 U/L
TBILI	40	1.195	-0.1	0.9411	0.0 – 1.6 mg/dL
DBIL	40	0.891	0.15	0.9785	0.0 – 1.7 mg/dL
CAL	60	0.942	0.42	0.9288	5.6 – 13.3 mg/dL
CREA	59	0.995	0.14	0.988	0.2 – 7.1 mg/dL
BUN	59	1	0.18	0.9875	2.2 – 36.1 mg/dL
TPRO	40	1.047	-0.05	0.9952	0.4 – 14.3 g/L
PHOS	60	1.17	-0.422	0.9758	2.7 – 8.7 mg/dL
CHOL	60	1.068	-9.3	0.9671	108 – 284 mg/dL
TRIG	60	1.044	21.7	0.9404	27 – 343 mg/dL
UA	60	0.901	0.164	0.9769	2.2 – 13.1 mg/dL
ALT	60	0.96	-0.9	0.9914	6 – 120 U/L

   b. *Matrix comparison:*
   Not applicable
3. Clinical studies:
   a. *Clinical Sensitivity:*
   Not Applicable
   b. *Clinical specificity:*
   Not Applicable
   c. Other clinical supportive data (when a. and b. are not applicable):
   Not Applicable
4. Clinical cut-off**:**
   Not applicable
5. Expected values/Reference range:
   See the package insert for each analyte.

N. Instrument Name:
Thermo Electron DataPro™ / DataPro Plus™ Clinical Chemistry Analyzer

O. System Descriptions:

1. <u>Modes of Operation</u>:
   - Profiles, batches, STAT procedures.
   - Automatic time adjust and dilution with high substrate consumption.
   - Automatic dilution for values above high limit.
   - Automatic repetition on abnormal low values.

2. <u>Software</u>:

   FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types:

   Yes ___X___ or No _____

3. <u>Specimen Identification</u>:

   Bar code option

4. <u>Specimen Sampling and Handling</u>:
   Sampling
   - 48 Sample positions in a rotary tray.
   - Use primary or pediatric tubes.
   - Bar code reader for sample identification (Optional).
   - Sample volume programmable 2 - 100 μL.
   - Pre-heater in the probe delivers reagent at the preset temperature.
   - Capacitive Level Sensor.
   - Inner and outer probe washing system.
   - CavroTM diluter syringe with valve assembly.
   Reagent Tray
   - 48 Reagent positions (Cooled in the Plus model).
   - Reagent volume Limits programmable:
   - In 0.6cm Cuvette
     First Reagent Volume   0 - 700 μL
     Second Reagent Volume 0 - 450 μL
     Minimum Volume 200 μL
     Maximum Volume 700 μL
     Total Volume (Sample + R1 + R2) 200 - 700 μL
   - Reagents are placed into wedge shaped vials: 45 mL, 30mL or 18mL, which can be used in any combination of single or two part reagent systems.
   Reaction Tray
   - Eighty (80) cuvette capacity.

- Double beam, Interferential filters.
- Wavelengths: 340, 380, 405, 450, 505, 550, 600, 650 and 700 nm.
- Bandwidth: 10 nm.
- Photometric range: -0.1 to 3.6 A (-0.1 to 5.5 A with 0.6 cm cuvettes).
- Lamp: Halogen, 6 volts, 20 watts.

5. Calibration:
   - End point with sample blank or reagent blank.
   - Calibration by Factor or Standard.
   - Priority programmable per sample (profile) or reagent (batch).
   - Calibration curves with two (2) to ten (10) standards.
   - Automatic curve adjust.
   - Fast and Two-Point Kinetics (0 and 1st order).

6. Quality Control:
   - Levy Jennings plots, Westgard rules.
   - Data import and export to other programs and/or remote terminals.
   - Automatic backup protection

P. Other Supportive Instrument Performance Characteristics Data Not Covered In The "Performance Characteristics" Section above:
Software documentation provided demonstrates the DataPro™ / DataPro Plus™ Analyzer was designed and manufactured under well developed software lifecycle processes.

Q. Proposed Labeling:
The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

R. Conclusion:
The submitted information in this premarket notification is complete and supports a substantial equivalence decision.