Thermo
ELECTRON CORPORATION

MAR 19 2007

510(k) SUMMARY

This Summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

The assigned 510(k) number is: k063150

A. Introduction:

According to the requirements of 21 CFR 807.92, the following information provides sufficent detail to understand the basis for a determination of substantial equivalence.

B. Submitter name

Thermo Electron Oy

C. Device name

Proprietary name: Complement C3
Common name: Complement C3
Classification: II
Class: Immunology
Product Code: CZW

Proprietary name: Complement C4
Common name: Complement C4
Classification: II
Class: Immunology
Product Code: CZW

D. Intended Use

For in vitro diagnostic use in the quantitative determination of the complement C3 concentration in human serum on the T60 analyzer.

For in vitro diagnostic use in the quantitative determination of the complement C4 concentration in human serum on the T60 analyzer.

SpeciCal

For in vitro diagnostic use on T60 analyzer. SpeciCal protein calibrator is used as a stock calibrator for both quantification of specific proteins in serum and plasma by immunoturbidimetry and for antigen excess detection using methods defined by Thermo Electron Oy.

SpeciTrol

For in vitro diagnostic use on T60 analyzer. SpeciTrol is intended to be used as an assayed control serum to monitor precision of specific protein tests defined by Thermo Electron Oy.

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Specitrol High
For in vitro diagnostic use on T60 analyzer. Specitrol High is intended to be used as an assayed control serum to monitor precision of specific protein tests defined by Thermo Electron Oy.

E. Indications for use

The complement C3 and complement C4 are intended for quantative in-vitro diagnostic determination of the complement C3 and C4 concentration in human serum using T60 Clinical Chemistry Analyzers. C3 and C4 measurements may aid in the diagnosis of immunologic disorders, especially those associated with deficiencies of complement components.

F. Substantial Equivalence

Bayer Corporation items:
Bayer Clinical Method for ADVIA 1650 Complement C3 (C3)
Bayer Clinical Method for ADVIA 1650 Complement C4 (C4)

Predicate device for the Specical calibrator:
Liquid Specific Protein Calibrator, Bayer USA, k033791.

Predicate devices for the Specitrol and Specitrol High controls:
Liquid Assayed Immunology Controls 1 and 3, Medical Analysis Systems USA, k960824.

G. Substantial equivalence -similarities

Complement C3 is substantially equivalent to other devices legally marketed in United States. We claim equivalence to the Bayer Clinical Method for ADVIA 1650 Complement C3 (C3)

Complement C4 is substantially equivalent to other devices legally marketed in United States. We claim equivalence to the Bayer Clinical Method for ADVIA 1650 Complement C4 (C4)

Specical is substantially equivalent to other devices legally marketed in United States. We claim equivalence to the Bayer Liquid Specific Protein Calibrator.

Specitrol and Specitrol High are substantially equivalent to other devices legally marketed in United States. We claim equivalence to the Medical Analysis Systems Liquid Assayed Immunology Controls 1 and 3.

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The following tables (Table 1 and Table 2) summarize comparative features of both test systems.

Table 1 **Complement C3**

Attribute	**New device #1**	**Predicate device #1**
Intented Use	For in vitro diagnostic use in the quantitative determination of the complement C3 concentration in human serum on the T60 analyzer.	This in vitro diagnostic assay is intended to measure the concentration of complement C3 in human serum on an ADVIA® Chemistry System. Measurement of Complement C3 levels is important in the determination of inherited or acquired deficiencies as well as the diagnosis of inflammatory and necrotic disorders.
Indication for Use	The complement C3 and complement C4 are intended for quantative in-vitro diagnostic determination of the complement C3 and C4 concentration in human serum using T60 Clinical Chemistry Analyzers. C3 and C4 measurements may aid in the diagnosis of immunologic disorders, especially those associated with deficiencies of complement components.	See intended use.
Assay Protocol	PEG enhanced immunoturbidimetric.	PEG enhanced immunoturbidimetric.
Tracebility/Standardization	The value of Complement C3 has been assigned by using IFCC preparate CRM 470 as a primary reference.	IRMM reference Material CRM 470 from IFCC was evaluated and found to recover 97% *of target concentration.*
Sample Type	Human serum	Human serum.
Reagent Storage	Reagents in unopened vials are stable at 2…8 °C until the expiration date printed on the label.	Unopened reagents are stable until the expiration date printed on the product label when stored at 2°C - 8°C and protected from light.

Expected Values	90 – 180 mg/dL	**Healthy adults:** 20 years 82-160 mg/dL 30 years 84-160 mg/dL 40 -70 years 90-170 mg/dL Newborns 58-108 mg/dL **Children**: 3 months 67-124 mg/dL 6 months 74-138 mg/dL 9 months 78-144 mg/dL 12 months 80-150 mg/dL 2-10 years 80-150 mg/dL 12-18 years 85-160 mg/dL
Instrument	T60i, T60i Kusti	ADVIA® 1650 Chemistry system.
Measuring Range	28* – 513 mg/d* (* The values are related to the Complement C3 concentration of the calibrator and are lot dependent.)	0.46 mg/dL to the C3 concentration in the Liquid Specific Protein Calibrator Level 6.
Precision	**Within run** Level 33 mg/dL SD = 0.5 CV% = 1.4 Level 42 mg/dL SD = 0.6 CV% = 1.3 Level 89 mg/dL SD = 0.7 CV(%) = 0.8 Level 216 mg/dL SD = 2.0 CV(%) = 0.9 Level 406 mg/dL SD = 3.4 CV% = 0.8 Level 441 mg/dL SD = 2.4 CV% = 0.5 **Between run** Level 33 mg/dL SD = 0.4 CV% = 1.2 Level 42 mg/dL SD = 0.6 CV% = 1.5 Level 89 mg/dL SD = 0.9 CV(%) = 1.0	**Within run** Level 64.02 mg/dL SD = 0.76 CV(%) = 1.2 Level 124.13 mg/dL SD = 2.56 CV(%) = 2.1 Level 182.35 mg/dL SD = 3.85 CV(%) = 2.1 **Total** Level 64.02 mg/dL SD = 4.16 CV(%) = 6.5 Level 124.13 mg/dL SD = 8.74 CV(%) = 7.0 Level 182.35 mg/dL SD = 12.16 CV(%) = 6.7

	Level 216 mg/dL SD = 1.2 CV(%) = 0.6 Level 406 mg/dL SD = 4.3 CV% = 1.1 Level 441 mg/dL SD = 5.2 CV% = 1.2 **Total** Level 33 mg/dL SD = 1.2 CV% = 3.7 Level 42 mg/dL SD = 1.3 CV% = 3.0 Level 89 mg/dL SD = 2.1 CV(%) = 2.3 Level 216 mg/dL SD = 5.3 CV(%) = 2.4 Level 406 mg/dL SD = 7.4 CV% = 1.8 Level 441 mg/dL SD = 9.0 CV% = 2.0	
Method Comparison	y = 0.98x + 4.99 R = 0.989 Range 28 to 299 mg/dL N = 102	**Bayer RA Complement C3 reagent run on ADVIA 1650** Serum Y = 1.06x-6.47 r = 0.952 N = 40 Sample Range 44.6 - 250.6 mg/dL

Limitations	**Lipemia**: No interference found up to 500 mg/dL (5 g/l) of Intralipid. **Hemolysate:** No interference found up to 1000 mg/dl (10 g/l) of hemoglobin. **Bilirubin, conjugated:** No interference found up to 58 mg/dL (1000 µmol/l) of conjugated bilirubin. **Bilirubin, unconjugated:** No interference found up to 58 mg/dl (1000 µmol/l) of unconjugated bilirubin.	The following interferences were tested up to the indicated levels and found not to interfere. Bilirubin (conjugated) ≤25 mg/dL Bilirubin (unconjugated) ≤18.75 mg/dL Hemoglobin ≤1000 mg/dL Triglyceride (concentrate) ≤1000 mg/dL

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The following table compares the Complement C4 with the predicate device.

Table 2 **Complement C4**

Attribute	**New device #1**	**Predicate device #1**
Intented Use	For *in vitro* diagnostic use in the quantitative determination of the complement C4 concentration in human serum on the T60 analyzer.	This *in vitro* diagnostic assay is intended to measure the concentration of complement C4 in human serum on an ADVIA® Chemistry System. Measurement of Complement C4 levels is important in the determination of inherited or acquired deficiencies as well as the diagnosis of inflammatory and necrotic disorders.
Indication for Use	The complement C3 and complement C4 are intended for quantative in-vitro diagnostic determination of the complement C3 and C4 concentration in human serum using T60 Clinical Chemistry Analyzers. C3 and C4 measurements may aid in the diagnosis of immunologic disorders, especially those associated with deficiencies of complement components.	See intended use
Assay Protocol	PEG enhanced immunoturbidimetric	PEG enhanced immunoturbidimetric
Tracebility/Standardization	The value of Complement C4 has been assigned by using IFCC preparate CRM 470 as a primary reference.	IRMM reference Material CRM-470 from IFCC was evaluated and found to recover 103% of target concentration.
Sample Type	Human serum	Human serum
Reagent Stability	Reagents in unopened vials are stable at 2 … 8 °C until the expiration date printed on the label.	Unopened reagents are stable until the expiration date printed on the product label whwn stored at 2°C - 8°C and protected from light.
Expected Values	10 – 40 mg/dl	12 – 36 mg/dL
Instrument	T60i, T60i Kusti	ADVIA® 1650 Chemistry system.
Measuring Range	6* – 103* mg/dl (* The values are related to the Complement C4 concentration of the calibrator and are lot dependent.).	From 0.36 mg/dL to the C3 concentration in the Liquid Specific Protein Calibrator Level 6

Precision	**Within run** Level 8 mg/dL SD = 0.1 CV(%) = 1.3 Level 8 mg/dL SD = 0.1 CV(%) = 1.5 Level 16 mg/dL SD = 0.3 CV(%) = 1.7 Level 46 mg/dL SD = 1.0 CV(%) = 2.2 Level 78 mg/dL SD = 0.8 CV(%) = 1.0 Level 88 mg/dL SD = 0.7 CV(%) = 0.8 **Between run** Level 8 mg/dL SD = 0.1 CV(%) = 1.6 Level 8 mg/dL SD = 0.1 CV(%) = 1.6 Level 16 mg/dL SD = 0.3 CV(%) = 1.5 Level 46 mg/dL SD = 0.9 CV(%) = 1.9 Level 78 mg/dL SD = 0.6 CV(%) = 0.7 Level 88 mg/dL SD = 0.7 CV(%) = 0.8 **Total** Level 8 mg/dL SD = 0.2 CV(%) = 2.8 Level 8 mg/dL SD = 0.2 CV(%) = 2.7 Level 16 mg/dL SD = 0.6 CV(%) = 3.5 Level 46 mg/dL SD = 2.0	**Within run** Level 19.03 mg/dL SD = 0.21 CV(%) = 1.1 Level 35.51 mg/dL SD = 0.58 CV(%) = 1.6 Level 51.70 mg/dL SD = 1.50 CV(%) = 2.9 **Total** Level 19.03 mg/dL SD = 0.76 CV(%) = 4.0 Level 35.51 mg/dL SD = 1.78 CV(%) = 5.0 Level 51.70 mg/dL SD = 2.66 CV(%) = 5.1

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	CV(%) = 4.4 Level 78 mg/dL SD = 1.4 CV(%) = 1.7 Level 88 mg/dL SD = 1.5 CV(%) = 1.7	
Method Comparison	y = 0.99x – 0.18 R = 0.995 Range 3 to 88 mg/dl N = 88	**Bayer RA Complement C4 reagent run on ADVIA 1650** Serum Y = 0.84x+2.33 r = 0.976 N = 50 Sample Range 10.1 – 59.1 mg/dL
Limitations	**Lipemia**: No interference found up to 300 mg/dL (3 g/l) of Intralipid®. **Hemolysate:** No interference found up to 1000 mg/dL (10 g/l) of hemoglobin. **Bilirubin, conjugated:** No interference found up to 58 mg/dL (1000 µmol/l) of conjugated bilirubin. **Bilirubin, unconjugated:** No interference found up to 58 mg/dL (1000 µmol/l) of unconjugated bilirubin.	The following interferences were tested up to the indicated levels and found not to interfere: Bilirubin (conjugated) ≤18.75 mg/dL Bilirubin (unconjugated) ≤18.75 mg/dL Hemoglobin ≤750 mg/dL Triglyceride (concentrate) ≤1000 mg/dL

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
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Thermo Electron Oy
c/o Päivi Sormunen
Vice President of QRC
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MAR 19 2007

Re: k063150
Trade/Device Name: Complement C3, Complement C4, Specical Calibrator, Specitrol Control, Specitrol High Control
Regulation Number: 21 CFR 866.5240
Regulation Name: Complement components immunological test system
Regulatory Class: Class II
Product Code: CZW, DBI, JIX, JJY
Dated: November 7, 2006
Received: February 7, 2007

Dear Päivi Sormunen:

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 the Code of Federal Regulations, Title 21, Parts 800 to 898. 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 Part 801); 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) 276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Robert L. Becker, Jr., M.D., Ph.D.
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

SpeciCal
For in vitro diagnostic use on T60 analyzer. SpeciCal protein calibrator is used as a stock calibrator for both quantification of specific proteins in serum and plasma by immunoturbidimetry and for antigen excess detection using methods defined by Thermo Electron Oy

SpeciTrol
For in vitro diagnostic use on T60 analyzer. SpeciTrol is intended to be used as an assayed control serum to monitor precision of specific protein tests defined by Thermo Electron Oy

Specitrol High
For in vitro diagnostic use on T60 analyzer. Specitrol High is intended to be used as an assayed control serum to monitor precision of specific protein tests defined by Thermo Electron Oy

Indications for Use

510(k) Number (if known): k063150

Device Names: **Complement C3**
Specical calibrator
Specitrol control
Specitrol High control

Indications for Use:

Complement C3 is intended for quantitative in-vitro diagnostic determination of the complement C3 concentration in human serum using T60 Clinical Chemistry Analyzers. C3 measurement may aid in the diagnosis of immunologic disorders, especially those associated with deficiencies of complement components.

SpeciCal
For in vitro diagnostic use on T60 analyzer. SpeciCal protein calibrator is used as a stock calibrator for both quantification of specific proteins in serum and plasma by immunoturbidimetry and for antigen excess detection using methods defined by Thermo Electron Oy

SpeciTrol
For in vitro diagnostic use on T60 analyzer. SpeciTrol is intended to be used as an assayed control serum to monitor precision of specific protein tests defined by Thermo Electron Oy

Specitrol High
For in vitro diagnostic use on T60 analyzer. Specitrol High is intended to be used as an assayed control serum to monitor precision of specific protein tests defined by Thermo Electron Oy

Prescription Use ____X___ (Part 21 CFR 801 Subpart D) 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)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

Page 1 of 1

510(k) K063150

Indications for Use

510(k) Number (if known): k063150

Device Names: **Complement C4**
Specical calibrator
Specitrol control
Specitrol High control

Indications for Use:

Complement C4 is intended for quantitative in-vitro diagnostic determination of the complement C4 concentration in human serum using T60 Clinical Chemistry Analyzers. C4 measurement may aid in the diagnosis of immunologic disorders, especially those associated with deficiencies of complement components.

SpeciCal
For in vitro diagnostic use on T60 analyzer. SpeciCal protein calibrator is used as a stock calibrator for both quantification of specific proteins in serum and plasma by immunoturbidimetry and for antigen excess detection using methods defined by Thermo Electron Oy

SpeciTrol
For in vitro diagnostic use on T60 analyzer. SpeciTrol is intended to be used as an assayed control serum to monitor precision of specific protein tests defined by Thermo Electron Oy

Specitrol High
For in vitro diagnostic use on T60 analyzer. Specitrol High is intended to be used as an assayed control serum to monitor precision of specific protein tests defined by Thermo Electron Oy

Prescription Use ____X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

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Division Sign-Off

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Page 1 of 1

510(k) K063150