DEC 0 4 2008

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: K080485.

A. Introduction:

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

B. Submitter's information

Name:	DiaSys Diagnostic Systems GmbH
Address:	Alte Strasse 9 65558 Holzheim Germany Telephone – 011 49 6432 9146 0 Fax – 011 49 6432 9146 32 www.diasys-diagnostics.com
Contact person:	Stephanie Klein, Import/Export Manager
Date of Preparation:	November 12, 2008

C. Device name

Proprietary name:	ASAT (GOT) FS assay
Common name:	Aspartate amino transferase (AST/SGOT) test system
Classification:	862.1100
Class:	II
Product Code:	CIT
Proprietary name:	TruCal U calibrator
Common Name:	Calibrator, Secondary
Classification:	862.1150
Class:	II
Product Code:	JIT
Proprietary name:	TruLab N and TruLab P controls
Common Name:	Quality control material (assayed and unassayed)
Classification:	862.1660
Class:	I
Product Code:	JJX

D. Predicate Device

Roche/Hitachi AST (ASAT/GOT) Aspartate aminotransferase acc. to IFCC with/without pyridoxal phosphate activation (k924244)

Roche Calibrator for automated systems (C.f.a.s.) (k990460).

Roche Precinorm Universal Plus and Precipath Universal Plus controls (k042389).

E. Device Description and Explanation of the Test

The DiaSys ASAT (GOT) FS assay is based on NADH reduction to NAD, as shown in the following equation:

L-Aspartate + 2-Oxoglutarate $\xrightarrow{ASAT}$ L-Glutamate + Oxalacetate

Oxalacetate + NADH + H^+ $\xrightarrow{MDH}$ L-Malate + NAD^+

Addition of pyridoxal-5-phosphate (P-5-P) stabilizes the transaminases and avoids falsely low values in samples containing insufficient endogenous P-5-P, e.g. from patients with myocardial infarction, liver disease and intensive care patients[1].

[1]Thomas L. Alanine aminotransferase (ALT), Aspartate aminotransferase (AST). In: Thomas L, editor. Clinical Laboratory Diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 55-65.

TruCal U calibrator – Serum based calibrator for use in the calibration of the quantitative DiaSys ASAT (GOT) FS assay on Hitachi 917.

TruLab N and TruLab P controls– Serum based control serum in normal and pathological range for use in quality control for monitoring accuracy and precision of the quantitative DiaSys ASAT (GOT) FS assay on Hitachi 917.

F. Intended Use / Indications For Use

ASAT (GOT) FS

The ASAT (GOT) FS assay is intended for quantitative *in vitro* diagnostic determination of the activity of the enzyme aspartate amino transferase (AST) in human serum and lithium heparin plasma on the Hitachi 917 instrument. Measurement of aspartate amino transferase levels aids in the diagnosis and treatment of certain types of liver and heart disease.

TruCal U

For *in vitro* diagnostic use on the Hitachi 917 instrument. TruCal U is used as a calibrator for the DiaSys ASAT (GOT) FS assay.

TruLab N and TruLab P Controls

For *in vitro* diagnostic use for quantitative testing on the Hitachi 917 instrument. TruLab N and TruLab P control sera are used to monitor accuracy and precision for the DiaSys ASAT (GOT) FS assay.

G. Substantial Equivalence

Similarities and Differences

The similarities and differences between the predicate and subject devices are provided below. Briefly, the ASAT assays, calibrators, and control material are similar with respect to intended use, functionality, and operating principle. Both assays are intended to operate as *in vitro* quantitative tests for the measurement of ASAT (GOT) on the Hitachi 917 instrument. Both calibrators are intended to calibrate their respective ASAT assays. Both control materials are intended to monitor the accuracy and precision of their respective ASAT assays.

The main differences are that the subject assay device is indicated only for human serum and lithium heparin plasma while the predicate assay device is indicated for human serum and both EDTA and Heparin plasma, the subject calibrator is indicated only for ASAT on the Hitachi 917 instrument while the predicate calibrator is a multi-analyte calibrator that can be used on a variety of instruments, and the subject controls are indicated only for ASAT on the Hitachi 917 instrument while the predicate controls are multi-analyte controls that can be used on a variety of instruments.

Conclusion

In summary, the DiaSys Diagnostic Systems ASAT (GOT) FS assay, TruCal U calibrator, and TruLab N and TruLab P controls devices described in this 510(k) are, in our opinion, substantially equivalent to the predicate devices. They have the same intended use and technological characteristics as the predicates, and raise no new issues of safety or effectiveness.

Comparison of Similarities and Differences

Comparative Characteristic or Feature	**Subject Device DiaSys ASAT (GOT) FS assay (K080485)**	**Predicate Device Roche/Hitachi 917 AST (ASAT/GOT) (K924244)**
Intended Use / Indications For Use	The ASAT (GOT) FS assay is intended for quantitative *in vitro* diagnostic determination of the activity of the enzyme aspartate amino transferase (AST) in human serum and lithium heparin plasma on the Hitachi 917 instrument. Measurement of aspartate amino transferase levels aids in the diagnosis and treatment of certain types of liver and heart disease.	In vitro test for the quantitative determination of aspartate aminotransferase (AST) in human serum or plasma on Roche clinical chemistry analyzers.
Assay Protocol	2-reagent method: modified IFCC reference method (without P-5-P) 2-reagent method: IFCC reference method (P-5-P concentrate mixed into R1)	2-reagent method: modified IFCC reference method (without P-5-P) 2-reagent method: IFCC reference method (P-5-P tablet mixed into R1)
Traceability	Standardized against the original IFCC formulation with and without pyridoxal phosphate.	same

Comparative Characteristic or Feature	Subject Device DiaSys ASAT (GOT) FS assay (K080485)	Predicate Device Roche/Hitachi 917 AST (ASAT/GOT) (K924244)
Reagent Storage	Storage: 2 – 8 °C Shelf Life R1 – 15 months R2 – 15 months P-5-P – 24 months On Board R1(no P-5-P) – 4 weeks R1(with P-5-P) – 6 days R2 - 4 weeks	Storage 2 – 8 °C Shelf Life R1 – up to expiration date R2 - up to expiration date P-5-P - up to expiration date On Board R1(no P-5-P) – 28 days R1(with P-5-P) – 6 days R2 – 90 days
Instrument	Hitachi 917	same
Measuring Range	7 – 700 U/L	4 – 800 U/L
Expected Values	With pyridoxal-5-phosphate activation Women < 31 U/L Men < 35 U/L Without pyridoxal-5-phosphate activation Women < 31 U/L Men < 35 U/L	Men: up to 40 U/L Women: up to 32 U/L
Precision	With P-5-P (N=80) Within Run Low serum: 1.08% Middle serum: 1.12% High serum: 0.93% Between Run Low serum: 2.42% Middle serum: 3.26% High serum: 0.14% Total Low serum: 2.84% Middle serum: 4.41% High serum: 1.22% Without P-5-P (N=80) Within Run Low serum: 1.32% Middle serum: 1.13% High serum: 0.83% Between Run Low serum: 3.19% Middle serum: 3.85% High serum: 0.57% Total Low serum: 3.81% Middle serum: 5.06% High serum: 1.30%	Within Run serum: 1.8% Low: 2.1% High: 1/1% Between Run serum: 3.2% Low: 3.2% High: 1.8%
Method Comparison	*With P-5-P* A comparison between DiaSys ASAT (GOT) FS with P-5-P (y) and a commercially available test (x) on Hitachi 917 using 139 serum samples in a range of 20 – 639 U/L gave following results: $y = 0.975 x + 4.414$ U/L; $r^2 = 0.9999$. *Without P-5-P* A comparison between DiaSys ASAT (GOT) FS without P-5-P (y) and a commercially available test (x) on Hitachi 917 using 139 serum samples in a range of 12 – 654 U/L gave following results: $y = 1.065 x + 0.215$ U/L; $r^2 = 0.9994$.	A comparison of the 10 µL sample volume AST assay (y) with the 20 µL assay using AST IFCC reagent from Roche on a Roche/Hitachi 911 analyzer gave the following correlation (U/L): Passing/Bablock: y=1.01x-0.93 Linear regression y=1.01x-0.75 r=1.000 Number of samples measured=91 Activity range: 11-690 U/L

<table>
<tr><th>Comparative Characteristic or Feature</th><th>Subject Device
DiaSys ASAT (GOT) FS assay
(K080485)</th><th>Predicate Device
Roche/Hitachi 917 AST (ASAT/GOT)
(K924244)</th></tr>
<tr><td>Interferences</td><td>Without P-5-P
<table><tr><th>Interference < 10% by</th><th colspan="2">Level ASAT [U/L]</th></tr><tr><td>Ascorbic acid up to 30 mg/dL</td><td>25.4</td><td>58.1</td></tr><tr><td>Conj. Bilirubin up to 60 mg/dL</td><td>22.3</td><td>55.8</td></tr><tr><td>Unconj. Bilirubin up to 24 mg/dL</td><td>22.4</td><td>54.1</td></tr><tr><td>Triglycerides up to 400 mg/dL</td><td>23.3</td><td>78.2</td></tr></table>
With P-5-P
<table><tr><th>Interference < 10% by</th><th colspan="2">Level ASAT [U/L]</th></tr><tr><td>Ascorbic acid up to 30 mg/dL</td><td>35.3</td><td>67.8</td></tr><tr><td>Conj. Bilirubin up to 36 mg/dL</td><td>31.2</td><td>66.9</td></tr><tr><td>Unconj. Bilirubin up to 24 mg/dL</td><td>31.5</td><td>65.9</td></tr><tr><td>Triglycerides up to 400 mg/dL</td><td>32.8</td><td>78.2</td></tr></table>
The lipid interference limit was assessed using an artificial lipid solution and does not necessarily correspond to the interference limit by native triglycerides. The presence of hemoglobin in serum indicates destruction of erythrocytes with release of ASAT, thus producing high interference.</td><td>Criterion: Recovery within ± 10% of initial value.

Hemolysis: 25 mg/dL,
Icterus: 60 mg/dL
Lipemia: L index of 500</td></tr>
</table>

Comparative Characteristic or Feature	Subject Device DiaSys TruCal U calibrator (K080485)	Predicate Device Roche Calibrator for automated systems (K990460)
Intended Use / Indications For Use	For *in vitro* diagnostic use on the Hitachi 917 instrument. TruCal U is used as a calibrator for the DiaSys ASAT (GOT) FS assay.	The Calibrator for automated systems (C.f.a.s.) is for use in the calibration of the quantitative Roche methods on Roche clinical chemistry analyzers as specified in the value sheets.
Matrix	Lyophilized human serum	Lyophilized human serum
Levels	Single level	same
Stability	Unopened: 17 months at 2-8°C Opened: 2 days at 2-8°C 8 hours at 25 °C 4 weeks at -20 °C (frozen only once)	Unopened: Stable at 2-8°C until expiration date Opened: 2 days at 2–8 °C
Traceability	ASAT target values in TruCal U are traceable to the International Federation of Clinical Chemistry (IFCC)	Traceability of the target values is given in the respective instructions for use of the system reagents.

Comparative Characteristic or Feature	Subject Device DiaSys TruLab N and TruLab P controls (K080485)	Predicate Device Roche Precinorm U and Precipath U controls (K042389)
Intended Use / Indications For Use	For *in vitro* diagnostic use for quantitative testing on the Hitachi 917 instrument. TruLab N and TruLab P control sera are used to monitor accuracy and precision for the DiaSys ASAT (GOT) FS assay.	Precinorm U Plus / Precipath U Plus are for use in quality control by monitoring accuracy and precision for the quantitative methods as specified in the enclosed value sheet
Matrix	Lyophilized human serum	same
Stability	Unopened: 36 months at 2-8°C Opened: 2 days at 2-8°C 8 hours at 25 °C 4 weeks at -20 °C (frozen only once)	Unopened: Until expiration date at 2-8°C. Opened: 12 hours at 15-25°C 5 days at 2-8°C 4 weeks at -15 to -25°C when frozen once

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DiaSys Diagnostic Systems GmbH
c/o Ms. Stephanie Klein
Import/Export Manager
Alte Strasse 9
D-65558 Holzheim, Germany

DEC 0 4 2008

Re: k080485
Trade/Device Name: ASAT (GOT) FS assay, TruCal U calibrator & TruLab N and TruLab P controls
Regulation Number: 21 CFR §862.1100
Regulation Name: Aspartate amino transferase (AST/SGOT) test system
Regulatory Class: Class II
Product Code: CIT, JIT, JJX
Dated: November 12, 2008
Received: November 14, 2008

Dear Ms. Klein:

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) 276-0490. 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 (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., 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

Indication for Use

510(k) Number (if known): K080485

Device Name: DiaSys ASAT (GOT) FS assay

Indication For Use:

ASAT (GOT) FS

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Prescription Use ___X___ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____ (21 CFR Part 801 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Carol C Benson

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K080485