510(k) Summary

This summary of 510(k) safety and effectiveness information is supplied in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510 (k) number is K090846

SEP - 8 2009

Date: September 2, 2009

Submitted by:

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Trade Name:

GSP Instrument
GSP Neonatal hTSH kit (3301-0010)

Common Name:

GSP Instrument (21 CFR 862.2560)

Regulation:

GSP Neonatal hTSH kit (21 CFR 862.1690)

Classification Name:

Fluorometer for clinical use (KHO)

Product Code:

Thyroid stimulating hormone radioimmunoassay (JLW)

Predicate device:

AutoDELFIA instrument (K935047)
AutoDELFIA Neonatal hTSH kit (K905710)

Device Description:

The GSP instrument (genetic screening processor) is a fully automated, high throughput batch analyzer for time-resolved and prompt fluorescence analysis of samples in microtitration plates. It is intended for in vitro quantitative and qualitative determination of analytes in body fluids. The GSP instrument and GSP chemistries are for professional use only.

The GSP™ Neonatal hTSH assay is a solid phase, two-site fluoroimmunometric assay based on the direct sandwich technique in which two monoclonal antibodies (derived from mice) are directed against two separate antigenic determinants on the hTSH molecule. Calibrators, controls and test specimens containing hTSH are reacted simultaneously with immobilized monoclonal antibodies

directed against a specific antigenic site on the ß hTSH subunit and europium-labeled monoclonal antibodies (directed against a different antigenic site located partly on the ß subunit and partly on the a subunit) in assay buffer. The assay buffer elutes hTSH from the dried blood spots on the filter paper disks. The complete assay requires only one incubation step.

DELFIA Inducer dissociates europium ions from the labeled antibody into solution where they form highly fluorescent chelates with components of DELFIA Inducer. The fluorescence in each well is then measured. The fluorescence of each sample is proportional to the concentration of hTSH in the sample.

Intended Use:

The GSP™ instrument is a fully automated, high throughput batch analyzer for time- resolved and prompt fluorescence analysis of samples in microtitration plates. It is intended for *in vitro* quantitative / qualitative determination of analytes in body fluids. The GSP instrument and GSP chemistries are for professional use only.

This kit (*GSP™ Neonatal hTSH*) is intended for the quantitative determination of human thyroid stimulating hormone (hTSH) in blood specimens dried on filter paper as an aid in screening newborns for congenital (neonatal) hypothyroidism using the GSP instrument.

Device Comparison:

Comparison of the GSP Instrument and GSP Neonatal hTSH devices with their respective predicates.

GSP Instrument		
Characteristics	**Proposed Device**	**AutoDELFIA Instrument (K935047)**
Intended Use/Indications for Use	The GSP™ instrument is a fully automated, high throughput batch analyzer for time resolved analysis of samples in microtitration plates. It is intended for *in vitro* quantitative / qualitative determination of analytes in body fluids. The GSP instrument and GSP chemistries are for professional use only.	The Wallac 1235 AutoDELFIA automatic immunoassay system is designed to automatically perform assays using the DELFIA technology. DELFIA is based on the proven and widely used method of time-resolved fluorometry.
Intended User	Same	Adequately trained laboratory personnel performing newborn screening
Test Mode	Same	Batch mode

Detection Technology	Same	Time-resolved fluoroimmunoassay
Sample Type	Dried blood spots	Dried blood spots, serum, plasma
Plate Capacity	24 plates	12 pates
Reagents	Individually bar-coded reagents	Reagent information on separate barcode labels
User Interface	GSP software –MicroSoft Windows Vista embedded - touch screen	AutoDELFIA Workstation software (MicroSoft Windows – resides on external PC – keyboard, mouse
Instrument Components	Instrument (consists of plate manipulator and modules). External PC Barcode rader.	Sample processor Plate processor External PC
GSP Neonatal hTSH kit		
Characteristics	**Proposed Device**	**AutoDELFIA Neonatal hTSH kit (K905710)**
Technology	Same	Time-resolved fluorescence
Sample Type	Same	Newborn Blood spot specimens
Calibrators	Same	Six levels of hTSH calibrators
Source	Same	Human whole blood with a hematocrit value of 50-55%
Matrix	Filter paper cassettes (Whatman no.903)	Filter paper sheets (Whatman no. 903)
Concentrations	Same	A 1 µU/mL blood B 10 µU/mL blood C 25 µU/mL blood D 50 µU/mL blood E 100 µU/mL blood F 250 µU/mL blood
Controls	Same	Two levels of hTSH controls
Source	Same	Human whole blood with a hematocrit value of 50-55%
Matrix	Filter paper cassettes (Whatman no.903)	Filter paper sheets (Whatman no. 903)
Concentrations	Same	Approx. values: C1 15 µU/mL blood C2 60 µU/mL blood
Tracer	Anti-h-TSH-Eu solution (~5 µg/mL); 3vials, 2.8 mL The tracer is Eu-N3-labeled antibody (clone 5409)	Anti-h-TSH-Eu stock solution (~20 µg/mL); 6vials, 1.1 mL The tracer is Eu-N1-labeled antibody (clone 5403)
Assay Buffer	Same	Neo hTSH Assay Buffer 3 bottles, 120 mL
Plates	Anti-hTSH Microtitration Strips (Nunc); 12 plates	Anti-hTSH Microtitration Strips (Thermo Electron); 12 plates
Detection	Same	Defined by analyte specific protocol
Calculation	GSP Workstation software,	Multicalc, X- axis LIN, Y-axis LIN ;

	X-axis LIN, Y-axis LIN; fitting algorithm spline smoothed	fitting algorithm spline smoothed
Incubation Detail	3,5 hours, 25°C	5 hours, 25°C

Analytical Performance Characteristics

Precision:
TSH:
Precision was determined in accordance with NCCLS (CLSI) document EP5-A2, Evaluation of Precision Performance of Quantitative Measurement Methods: Approved Guideline – Second Edition.

The variation of the 3301-0010 GSP Neonatal hTSH assay was determined using spiked dry whole blood spot samples, 3 kit lots and 3 GSP systems. The study was performed over 23 days in 27 runs each consisting of 2 plates with 4 replicates per sample. The analysis of variance approach was used to calculate the following:

Precision data using a full calibration curve on each plate:

Sample	Total mean value µU/mL blood	Within-run variation (% CV)	Within-lot variation (% CV)	Total variation (% CV)
1	10.5	6.8	8.9	10.1
2	23.2	5.9	8.6	8.9
3	102	6.1	8.3	8.5
4	241	6.4	8.4	8.7

Precision data using one calibration curve valid for 24 h:

Sample	Total mean value µU/mL blood	Within-run variation (% CV)	Within-lot variation (% CV)	Total variation (% CV)
1	10.6	7.0	8.7	9.9
2	23.4	6.1	8.0	8.3
3	102	6.2	7.7	7.7
4	241	6.8	7.7	7.9

Linearity:
TSH:
Linearity was determined in accordance with NCCLS (CLSI) document EP6-A, Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach, Approved Guideline. For hTSH, the method has been demonstrated to be linear from 0.66 µU/mL to 375 µU/mL blood.

Detection Limit:
TSH:
The limits of blank, detection and quantitation were determined in accordance with NCCLS (CLSI) document EP17-A, Protocols for Determination of Limits of Detection and Limits of Quantitation; Approved Guideline.

The Limit of Blank (LoB) for GSP neonatal hTSH kit is 0.96 µU/mL blood, defined as the 95th percentile of a distribution of blank samples (n=216). The Limit of Detection (LoD) is 1.31 µU/mL blood based on 432 determinations, 72 blank and 216 low level samples. The Limit of Quantitation (LoQ) is 1.31 µU/mL blood, defined as the lowest concentration with a total CV <20%.

Analytical Specificity:
TSH:
Icteric (unconjugated bilirubin ≤ 342 µmol/L, equivalent to 20 mg/dL in blood, and conjugated bilirubin ≤ 237 µmol/L, equivalent to 20 mg/dL in blood) samples do not interfere with the assay. Lipemic samples (Intralipid ≤ 10 mg/mL in blood) do not interfere with the assay. Additional hemoglobin up to 15 g/L does not interfere with the assay.

Cross reactivity was determined in accordance with CLSI document EP7-A2, Interference Testing in Clinical Chemistry; Approved Guideline – Second Edition.

For the GSP Neonatal hTSH kit, the cross reactivity with other substances is presented in the following table:

Antigen	Added concentration	Measured apparent TSH concentration (µU/mL blood)	Measured TSH concentration without interferent (µU/mL blood)
hFSH	0.25 U/mL	19.2	18.7
		30.3	30.1
hLH	0.25 U/mL	16.2	15.4
		30.3	30.7
hCG	100 U/mL	14.5	15.5
		28.3	28.8

Comparison Studies:

TSH:

Samples were categorized in accordance with the cut-off recommendations for TSH measurements found in the 2006 Update of Newborn Screening and Therapy of Congenital Hypothyroidism by the American Academy of Pediatrics (AAP).

Site 1:

The table below shows the distribution into the test results categories for the GSP and predicate assays separately.

Distribution of samples into test results categories

hTSH	Normal (<20µU/mL serum)	Borderline (20-40 µU/mL serum)	Hypothyroid (>40µU/mL serum)
GSP	1978	53	22
Predicate	1970	61	22

Of the diagnosed positive samples (n=20) both the GSP and predicate classified all samples as hypothyroid as can be seen in the table below.

Classification of diagnosed positive samples

Classification of diagnosed positive samples	Normal (<20µU/mL serum)	Hypothyroid (>40µU/mL serum)
GSP	0	20
Predicate	0	20

The following table shows how the GSP and predicate have classified the same samples. It can be seen from the table some samples are exchanged between the borderline and normal samples but both methods classify the same samples as hypothyroid.

Distribution of samples into test results categories: GSP vs predicate

hTSH	Predicate			
GSP	**Normal**	**Borderline**	**Hypothyroid**	**Total**
Normal	1958	20	0	1978
Borderline	12	41	0	53
Hypothyroid	0	0	22	22
Total	1970	61	22	2053

The overall percent agreement, the positive agreement and negative agreement are calculated along with 95% confidence intervals (95% CI). Results are presented in the table below and they show good agreement between methods.

The overall percent agreement, positive agreement and negative agreement

	Numerator	Denominator	Percent Agreement*	95%CI*
Overall percent agreement	1958+41+22	2053	98.4%	97.9%-99.0%
Positive agreement	41+22	61+22	75.9%	66.1%-85.7%
Negative agreement	1958	1970	99.4%	99.0%-99.8%

* In these calculations the borderline results are considered as positive.

Site 2:

The table below shows the distribution into the test results categories for the GSP and predicate assays separately.

Distribution of samples into test results categories

hTSH	Normal (<20µU/mL serum)	Borderline (20-40 µU/mL serum)	Hypothyroid (>40µU/mL serum)

GSP	2023	56	25
Predicate	2011	67	26

Of the known positive samples (n=26) one sample (#20082070164) was classified as borderline by both the GSP and predicate assays. This sample was initially a borderline sample but a repeat sample tested was classified as hypothyroid as can be seen below.

Classification of diagnosed positive samples

Classification of diagnosed positive samples	Normal (<20μU/mL serum)	Borderline (20-40 μU/mL serum)	Hypothyroid (>40μU/mL serum)
GSP	0	1*	25
Predicate	0	1*	25

* Sample initial result was borderline (27 μU/mL serum)

The table below shows how the GSP and predicate assays have classified the same samples. It can be seen from the table some samples are exchanged between the borderline and normal classifications.

Distribution of samples into test results categories: GSP vs Predicate

hTSH	Predicate			
GSP	**Normal**	**Borderline**	**Hypothyroid**	**Total**
Normal	2000	22	1	2023
Borderline	11	45	0	56
Hypothyroid	0	0	25	25
Total	2011	67	26	2104

The overall percent agreement, the positive agreement and the negative agreement are calculated along with 95% confidence intervals (95% CI). Results are presented in the table below and they show good agreement between methods.

The overall percent agreement, positive agreement and negative agreement

	Numerator	Denominator	Percent Agreement	95%CI
Overall percent agreement	2000+45+25	2104	98.4%	97.8%-98.9%
Positive agreement	45+25	67+26	75.3%	66.0%-84.6%
Negative agreement	2000	2011	99.5%	99.1%-99.8%

Internal Method Comparison

The 3301-001U GSP Neonatal hTSH kit was compared with the B032-312 AutoDELFIA Neonatal hTSH kit using routine screening and spiked blood spot samples, single measurements, in the range of 1.38 – 250 uU/mL blood in the 3301-001U kit. The correlation from a weighted Deming regression was found to be;

$Y = 0.97x - 0.21$ 95% CI slope (0.94, 1.01), intercept (-0.37, -0.16) N=162

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

PerkinElmer, Inc.
c/o Ms. Kay A. Taylor
Senior Manager, Regulatory Affairs
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Indianapolis, IN 46236

SEP - 3 2009

Re: k090846
Trade/Device Name: GSP Neonatal hTSH kit
Regulation Number: 21 CFR § 862.1690
Regulation Name: Thyroid stimulating hormone test system
Regulatory Class: Class II
Product Code: JLW, KHO
Dated: August 14, 2009
Received: August 18, 2009

Dear Ms. Taylor:

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney C. Harper, Ph.D.
Acting 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): k090846

Device Name: **GSP Neonatal hTSH kit**

Indication For Use:

This kit is intended for the quantitative determination of human thyroid stimulating hormone (hTSH) in blood specimens dried on filter paper as an aid in screening newborns for congenital (neonatal) hypothyroidism using the GSP instrument.

Prescription Use **XXX** And/Or Over the Counter Use ____.
(21 CFR Part 801 Subpart D) (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)

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

510(k) k090846

Indications for Use Form

510(k) Number (if known): **K090846**

Device Name: **GSP Instrument**

Indications for Use:

The GSP™ Instrument is a fully automated, high throughput batch analyzer for time resolved analysis of samples in microtitration plates. It is in intended for *in vitro* quantitative / qualitative determination of analytes in body fluids.

Prescription Use XXXX (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 OF NEEDED)

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

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

510(k) K090846