510(k) SUMMARY

JUL 2 3 2010

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: K100682

Date: July 13, 2010

Submitted by:
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Trade Name:
GSP® Neonatal 17α-OH-progesterone kit (3305-001U)

Common Name:
GSP Neonatal 17-OHP kit

Regulation:
21 CFR 862.1395

Classification Name:
Radioimmunoassay, 17-Hydroxyprogesterone

Product Code:
JLX

Predicate Device:
AutoDELFIA® Neonatal 17α-OH-progesterone kit, 510(k) Number (K081922)

Device Description:
The GSP Neonatal 17α-OH-progesterone (17-OHP) assay is a solid phase, time-resolved fluoroimmunoassay based on the competitive reaction between europium-labeled 17-OHP and sample 17-OHP for a limited amount of binding sites on 17-OHP specific polyclonal antibodies (derived from rabbit). Danazol facilitates the release of 17-OHP from the binding proteins. A second antibody, directed against rabbit IgG, is coated to the solid phase, giving convenient separation of the antibody-bound and free antigen.

DELFIA Inducer dissociates europium ions from the labeled antigen 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 inversely proportional to the concentration of 17-OHP in the sample.

Intended Use:

The GSP Neonatal 17α-OH-progesterone kit is intended for the quantitative determination of human 17α-OH-progesterone in blood specimens dried on filter paper as an aid in screening newborns for congenital adrenal hyperplasia (CAH) using the GSP™ instrument.

Substantial Equivalence:

The GSP Neonatal 17α-OH-progesterone kit is substantially equivalent to our currently marketed AutoDELFIA Neonatal 17α-OH-progesterone kit (K081922). There are the following similarities and differences between the two kits:

Table 1. Characteristics of the two kits.

Characteristic	**GSP Neonatal 17OHP kit (New Device)**	**AutoDELFIA Neonatal 17OHP (Predicate Device)**
Similarities		
Intended User	Adequately trained laboratory personnel in laboratories performing newborn screening	Same
Intended Use / Indications for Use	The GSP Neonatal 17α-OH-progesterone kit is intended for the quantitative determination of human 17α-OH-progesterone in blood specimens dried on filter paper as an aid in screening newborns for congenital adrenal hyperplasia (CAH) using the GSP™ instrument.	The AutoDELFIA Neonatal 17α-OH-progesterone kit is intended for the quantitative determination of human 17α-OH-progesterone in blood specimens dried on filter paper as an aid in screening newborns for congenital adrenal hyperplasia (CAH) using the 1235 AutoDELFIA automatic immunoassay system.
Chemical Principle	Competitive reaction between europium labeled 17-OHP and sample 17-OHP for a limited number of binding sites on 17-OHP specific polyclonal antibodies derived from rabbit	Same
Detection principle	Time-resolved fluorescence	Same
Specimen	Filter paper disks with a diameter of approximately 3.2 mm (1/8 inch)	Same
Antibodies	Rabbit polyclonal antibodies	Same
Calibrator and Control Matrix	Human blood with a hematocrit of 50-55% and spotted onto filter paper cassettes (Whatman, no. 903)	Same
Calibration	Calibrated using gravimetric methods	Same
Controls	3 levels (approx. values 17, 45 and 100 ng/mL serum)	Same
Assay Buffer	17-OHP Assay Buffer, ready for use	Same
Coated Plates	Anti-rabbit IgG Microtitration Strips, 8 x 12 wells coated with anti-rabbit IgG (raised in goat)	Same
Calibrators	6 levels (approx. values 0, 4, 10, 25, 75 and 220 ng/mL serum)	Same

Characteristic, continued	**GSP Neonatal 17OHP kit (New Device)**	**AutoDELFIA Neonatal 17OHP (Predicate Device)**
	Differences	
Instrument	GSP Instrument	1235 AutoDELFIA Instrument
Dissociation solution	DELFIA Inducer	Enhancement Solution
Antibody Cross-Reactions in the Assay	17α-OH pregnenolone sulfate 0.77 % 11-Deoxycortisol 0.49 % 17α-OH pregnenolone 0.80 % Progesterone 0.20 % 21-Deoxycortisol 0.84% Deoxycorticosterone 0.01%	17α-OH pregnenolone sulfate 0.78 % 11-Deoxycortisol 0.62 % 17α-OH pregnenolone 0.83 % Progesterone 0.37 % 21-Deoxycortisol 0.91% Deoxycorticosterone 0.02%
Measuring Range Linearity Range	1.4 to 220 ng/mL serum 1.4-229 ng/mL serum	Same 1.4-235 ng/mL serum
Tracer	17-OHP-Eu tracer stock solution, approximate concentration of 6 nmol/L, ready-to-use	17-OHP-Eu tracer stock solution, approximate concentration of 40 nmol/L, lyophilized
Analytical Sensitivity / Limit of Blank, Limit of Detection	Limit of Blank 0.42 ng/mL serum Limit of Detection 1.4 ng/mL serum	Limit of Blank 0.37 ng/mL serum Limit of Detection 0.84 ng/mL serum
Precision (Total Variation using a full calibration curve on each plate)	3.2 ng/mL serum CV% 14.9 5.3 ng/mL serum CV% 13.9 16.9 ng/mL serum CV% 11.3 51.6 ng/mL serum CV% 9.4 92.5 ng/mL serum CV% 10.9 131 ng/mL serum CV% 10.1 161 ng/mL serum CV% 10.9 187 ng/mL serum CV% 12.0	2.12 ng/mL serum CV% 13.0 4.69 ng/mL serum CV% 9.8 7.52 ng/mL serum CV% 14.8 27.0 ng/mL serum CV% 8.3 54.4 ng/mL serum CV% 9.2 109 ng/mL serum CV% 10.8 182 ng/mL serum CV% 9.1
Expected Values in Newborns (per birth weight and 95th percentile)	< 1250 g 94.1 ng/mL serum 1250-2249 g 47.5 ng/mL serum ≥ 2250 g 13.8 ng/mL serum	Site 1: < 1250 g 73.6 ng/mL serum 1250-2249 g 40.8 ng/mL serum ≥ 2250 g 20.9 ng/mL serum Site 2: < 1250 g 95.0 ng/mL serum 1250-2249 g 68.6 ng/mL serum ≥ 2250 g 28.3 ng/mL serum
Endogenous Interferences	Icteric (unconjugated bilirubin ≤ 342 µmol/L, equivalent to 20 mg/dL and conjugated bilirubin ≤ 237 µmol/L, equivalent to 20 mg/dL), Hemolytic (additional hemoglobin ≤ 0.5 g/dL), Lipemic (Intralipid ≤ 3000 mg/dL at 17OHP levels of 30 and 70 ng/mL and Intralipid ≤ 750 mg/dL at 17OHP levels of 150 ng/mL) specimens do not interfere with the assay.	Icteric (unconjugated bilirubin ≤ 342 µmol/L, equivalent to 20 mg/dL and conjugated bilirubin ≤ 237 µmol/L, equivalent to 20 mg/dL), Hemolytic (additional hemoglobin ≤ 0.5 g/dL). Lipemic (Intralipid ≤ 3000 mg/dL) specimens do not interfere with the assay.
Method Comparison	The GSP kit (y) was compared to the AutoDELFIA kit (x) with 2567 samples over a range of 1.4 – 220 ng/mL serum. Y= 0.97x + 0.27; r = 0.96;	

Screening Efficacy:

The GSP kit and the predicate device were compared in one newborn screening laboratory using retrospective archived specimens and leftover samples from specimens submitted for routine screening. A total of 23 known CAH cases were included in the 2589 samples evaluated. The results are presented in tables 2 -7 using the 90^{th}, 95^{th} and 99^{th} percentile cut-offs.

Table 1 Distribution of specimens into GSP and AutoDELFIA test results categories when using the highest 90% percentile cutoff. The agreement-%:s with 95% CIs are also presented (≥2500g).

90% cutoff	AutoDELFIA		
GSP	Test Positive	Test Negative	Total
Test Positive	165	39	204
Test Negative	36	1602	1638
Total	201	1641	1842

Overall percent agreement = (165+1602)/1842*100% = 95.9% (CI 94.9%-96.8%)
Positive percent agreement = (165/201)*100% = 82.1% (CI 76.1%-87.1%)
Negative percent agreement = (1602/1641)*100%= 97.6% (CI 96.8%-98.3%)

Table 2 Distribution of specimens into GSP and AutoDELFIA test results categories when using the highest 90% percentile cutoff. The agreement-%:s with 95% CIs are also presented (1250g-2249g).

90% cutoff	AutoDELFIA		
GSP	Test Positive	Test Negative	Total
Test Positive	42	3	45
Test Negative	3	391	394
Total	45	394	439

Overall percent agreement = (42+391)/(439)*100% = 98.6% (CI 97.0%-99.5%)
Positive percent agreement = (42/45)*100% = 93.3% (CI 81.7%-98.6%)
Negative percent agreement = (391/394)*100%= 99.2% (CI 97.8%-99.8%)

Table 3 Distribution of specimens into GSP and AutoDELFIA test results categories when using the highest 90% percentile cutoff. The agreement-%:s with 95% CIs are also presented (<1250g).

90% cutoff	AutoDELFIA		
GSP	Test Positive	Test Negative	Total
Test Positive	25	6	31
Test Negative	6	271	277
Total	31	277	308

Overall percent agreement = (25+271)/(308)*100% = 96.1% (CI 93.3%-98.0%)
Positive percent agreement = (25/31)*100% = 80.6% (CI 62.5%-92.5%)
Negative percent agreement = (271/277)*100%= 97.8% (CI 95.3%-99.2%)

Table 4 Distribution of specimens into GSP and AutoDELFIA test results categories when using the highest 95% percentile cutoff. The agreement-%:s with 95% CIs are also presented (≥2500g).

95% cutoff	AutoDELFIA		
GSP	Test Positive	Test Negative	Total
Test Positive	95	16	111
Test Negative	18	1713	1731
Total	113	1729	1842

Overall percent agreement = (95+1713)/1842*100% = 98.2% (CI 97.4%-98.7%)
Positive percent agreement = (95/113)*100% = 84.1% (CI 76.0%-90.3%)
Negative percent agreement = (1713/1729)*100%= 99.1% (CI 98.5%-99.5%)

Table 5 Distribution of specimens into GSP and AutoDELFIA test results categories when using the highest 95% percentile cutoff. The agreement-%:s with 95% CIs are also presented (1250g-2249g).

95% cutoff	AutoDELFIA		
GSP	Test Positive	Test Negative	Total
Test Positive	20	3	23
Test Negative	3	413	416
Total	23	416	439

Overall percent agreement = (20+413)/439*100% = 98.6% (CI 97.0%-99.5%)
Positive percent agreement = (20/23)*100% = 87.0% (CI 66.4%-97.2%)
Negative percent agreement = (413/416)*100%= 99.3% (CI 97.9%-99.9%)

Table 6 Distribution of specimens into GSP and AutoDELFIA test results categories when using the highest 95% percentile cutoff. The agreement-%:s with 95% CIs are also presented (<1250g).

95% cutoff	AutoDELFIA		
GSP	Test Positive	Test Negative	Total
Test Positive	11	5	16
Test Negative	5	287	292
Total	16	292	308

Overall percent agreement = (11+287)/308*100% = 96.8% (CI 94.1%-98.4%)
Positive percent agreement = (11/16)*100% = 68.8% (CI 41.3%-89.0%)
Negative percent agreement = (287/292)*100%= 98.3% (CI 96.0%-99.4%)

Table 7 Distribution of specimens into GSP and AutoDELFIA test results categories when using the highest 99% percentile cutoff. The agreement-%:s with 95% CIs are also presented (≥2500g).

99% cutoff	AutoDELFIA		
GSP	Test Positive	Test Negative	Total
Test Positive	39	2	41
Test Negative	1	1800	1801
Total	40	1802	1842

Overall percent agreement = (39+1800)/1842*100% = 99.8% (CI 99.5%-100%)
Positive percent agreement = (39/40)*100% = 97.5% (CI 86.8%-99.9%)
Negative percent agreement = (1800/1802)*100%= 99.9% (CI 99.6%-100%)

Table 8 Distribution of specimens into GSP and AutoDELFIA test results categories when using the highest 99% percentile cutoff. The agreement-%:s with 95% CIs are also presented (1250g-2249g).

99% cutoff	AutoDELFIA		
GSP	Test Positive	Test Negative	Total
Test Positive	2	4	6
Test Negative	4	429	433
Total	6	433	439

Overall percent agreement = (2+429)/439*100% = 98.2% (CI 96.4%-99.2%)
Positive percent agreement = (2/6)*100% = 33.3% (CI 4.3%-77.7%)
Negative percent agreement = (429/433)*100%= 99.1% (CI 97.7%-99.7%)

Table 1 Distribution of specimens into GSP and AutoDELFIA test results categories when using the highest 99% percentile cutoff. The agreement-%:s with 95% CIs are also presented (<1250g).

99% cutoff	AutoDELFIA		
GSP	Test Positive	Test Negative	Total
Test Positive	4	0	4
Test Negative	0	304	304
Total	4	304	308

Overall percent agreement = (4+304)/308*100% = 100% (CI 98.8%-100%)
Positive percent agreement = (4/4)*100% = 100% (CI 39.8%-100%)
Negative percent agreement = (304/304)*100%= 100% (CI 98.8%-100%)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food & Drug Administration
10903 New Hampshire Avenue
Building 66
Silver Spring, MD 20993

JUL 23 2010

Wallac Oy
Subsidiary of PerkinElmer
c/o Kay A. Taylor
Director, Regulatory and Clinical Affairs
8275 Carloway Road
Indianapolis, IN 46236

Re: k100682
Trade/Device Name: GSP Neonatal 17α-OH-progesterone kit (3305-001U)
Regulation Number: 21 CFR §862.1395
Regulation Name: 17-Hydroxyprogesterone Test System
Regulatory Class: Class I; meets limitations of exemptions under 21 CFR § 862.9 (c)(2)
Product Code: JLX
Dated: June 3, 2010
Received: June 7, 2010

Dear Kay A. 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.
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 Form

510(k) Number (if known): k100682

Device Name: GSP® Neonatal 17α-OH-progesterone kit (3305-001U)

Indications for Use:

The GSP Neonatal 17α-OH-progesterone kit is intended for the quantitative determination of human 17α-OH-progesterone in blood specimens dried on filter paper as an aid in screening newborns for congenital adrenal hyperplasia (CAH) using the GSP™ instrument.

Prescription Use ___X___ (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)

Carol C. Benson

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

510(k) K100682