510(k) SUMMARY

APR 2 2 2011

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: ____K103484_____

Date: April 12, 2011

Submitted by:

Wallac Oy, subsidiary of PerkinElmer
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Trade Name: GSP® Neonatal Thyroxine (T_4) kit (3302-001U)

Common Name: GSP Neonatal Thyroxine (T_4) kit

Regulation: 21 CFR 862.1700

Classification Name: Total Thyroxine Test System

Product Code: KLI

Predicate Device: AutoDELFIA® Neonatal Thyroxine T4
510(k) Number (K943416)

Device Description: The GSP Neonatal T4 assay is a solid phase time-resolved fluoroimmunoassay based on the competitive reaction between europium-labeled T4 and sample T4 for a limited amount of binding sites on T4 specific monoclonal antibodies (derived from mice). The use of 8-anilino-1-naphthalenesulfonic acid (ANS) and salicylate in the T4 Assay Buffer facilitates the release of T4 from the binding proteins. Thus the assay measures the total amount of T4 in the test specimen. A second antibody, directed against mouse IgG, is coated to the solid phase, and binds the IgG-thyroxine complex, giving convenient separation of the antibody-bound and free antigen.

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 inversely proportional to the concentration of T4 in the sample.

Intended Use:

The GSP Neonatal IRT kit is intended for the quantitative determination of human thyroxine (T4) in blood specimens dried on filter paper as an aid in screening newborns for congenital (neonatal) hypothyroidism using the GSP® instrument.

Substantial Equivalence:

The GSP® Neonatal Thyroxine (T_4) kit is substantially equivalent to our currently marketed AutoDELFIA® Neonatal Thyroxine T4 (K943416). There are the following similarities and differences between the two kits:

Predicate Device	FEATURE	Similarities (AutoDELFIA T4)	Differences (GSP T4)
AutoDELFIA Neonatal T4 Kit	Intended User	Adequately trained laboratory personnel in laboratories performing newborn screening.	Same
AutoDELFIA Neonatal T4 Kit	Intended use	This kit is intended for the quantitative determination of human thyroxine (T4) in blood specimens dried on filter paper as an aid in screening newborns for congential (neonatal) hypothyroidism using the AutoDELFIA automatic immunoassay system.	The kit is intended for the quantitative determination of human thyroxine (T4) in blood specimens dried on filter paper as an aid in screening newborns for congenital (neonatal) hypothyroidism using the GSP instrument.
AutoDELFIA Neonatal T4 Kit	Chemical Principle	The Neonatal T4 assay is a solid phase time-resolved fluoroimmunoassay based on the competitive reaction between europium-labeled T4 and sample T4 for a limited amount of binding sites on T4 specific monoclonal antibodies (derived from mice). The use of 8-anilino-1-naphthalenesulfonic acid (ANS) and salicylate in the T4 Assay Buffer facilitates the release of T4 from the binding proteins. Thus the assay measures the total amount of T4 in the test specimen. A second antibody, directed against mouse IgG, is coated to the solid phase, and binds the IgG-thyroxine complex, giving convenient separation of the antibody-bound and free antigen. Europium ions are dissociated from the labeled antibody into solution where they form highly fluorescent chelates with components of the dissociation solution. The fluorescence in each well is then measured. The fluorescence of each sample is inversely proportional to the concentration of T4 in the sample	Same
AutoDELFIA Neonatal T4 Kit	Dissociation Solution	Enhancement Solution.	DELFIA Inducer
AutoDELFIA Neonatal T4 Kit	Detection Principle	Time-resolved fluorescence	Same
AutoDELFIA Neonatal T4 Kit	Specimen	Dried blood on filter paper disks with a diameter of approximately 3.2 mm (1/8 inch)	Same
AutoDELFIA Neonatal T4 Kit	Antibodies	Primary mouse monoclonal antibody and secondary rabbit polyclonal antibody	Same

Predicate Device	FEATURE	Similarities (AutoDELFIA T4)	Differences (GSP T4)
AutoDELFIA Neonatal T4 Kit	Calibrators	Six levels of T4 calibrators	Same
AutoDELFIA Neonatal T4 Kit	Source	Human blood with a hematocrit value of 50-55%	Same
AutoDELFIA Neonatal T4 Kit	Matrix	Filter paper sheets (Whatman no. 903)	Filter paper cassettes (Whatman no.903)
AutoDELFIA Neonatal T4 Kit	Calibrator Concentrations	A 0 µg/dL serum B 2 µg/dL serum C 4 µg/dL serum D 8 µg/dL serum E 16 µg/dL serum F 30 µg/dL serum	Same
AutoDELFIA Neonatal T4 Kit	Controls	Three levels of T4 controls	Same
AutoDELFIA Neonatal T4 Kit	Control Concentrations	Approx. values: C1 3 µg/dL serum C2 7 µg/dL serum C3 12 µg/dL serum	Same
AutoDELFIA Neonatal T4 Kit	Tracer	T4-Eu (~25 nmol/L); 6 vials, lyophilized	T4-Eu (~10 nmol/L); 3 vials, 2.8 mL Different europium chelate
AutoDELFIA Neonatal T4 Kit	Antibody	T4 antibody stock solution (~40 nmol/L); 6 vials, 1.5 mL	T4 antibody (~12 nmol/L); 3 vials, 2.8 mL
AutoDELFIA Neonatal T4 Kit	Assay Buffer	T4 Assay Buffer 3 bottles, 110 mL	Same
AutoDELFIA Neonatal T4 Kit	Plates	Anti-Mouse IgG Microtitration strips (Nunc PolySorb) ; 12 plates	Anti-Mouse IgG Microtitration strips (Nunc MaxiSorb) ; 12 plates
AutoDELFIA Neonatal T4 Kit	Detection	Defined by analyte specific protocol	Same
AutoDELFIA Neonatal T4 Kit	Calculation	Multicalc, X- axis LOG, Y-axis B/B_{Max} ; fitting algorithm spline smoothed	GSP Workstation software, X-axis Hyberbolic, Y-axis Bound2Max; fitting algorithm spline smoothed
AutoDELFIA Neonatal T4 Kit	Incubation Detail	11min + 2 hours, 25°C	10 min + 2 hours, 25°C
AutoDELFIA Neonatal T4 Kit	Precision (levels/CVs)	Full standard curve on each plate: Control 1; 3.95 µg/dL serum Intra-assay variation 14.9 % Inter-assay variation 10.0 % Total variation 18.0 %	Full calibration curve on each plate: Sample 1; 2.0 µg/dL Within run 11.0% Within lot 15.5% Total variation 15.8%

Predicate Device	FEATURE	Similarities (AutoDELFIA T4)	Differences (GSP T4)
		Control 2; 8.08 µg/dL serum Intra-assay variation 10.6 % Inter-assay variation 7.1 % Total variation 12.7 % Control 3; 18.2 µg/dL serum Intra-assay variation 8.2% Inter-assay variation 4.3% Total variation 9.3 %	Sample 2; 4.8 µg/dL Within run 7.3% Within lot 10.7% Total variation 11.4% Sample 3; 7.5 µg/dL Within run 6.5% Within lot 8.4% Total variation 8.6% Sample 4; 16.6 µg/dL Within run 4.5% Within lot 7.8% Total variation 8.5% Sample 5; 19.8 µg/dL Within run 7.2% Within lot 9.9% Total variation 10.3% Sample 6; 21.4 µg/dL Within run 7.1% Within lot 9.8% Total variation 10.1%
AutoDELFIA Neonatal T4 Kit	Measuring Range	1.5 µg/dL to the highest level calibrator	1.6 to 30 µg/dL serum
AutoDELFIA Neonatal T4 Kit	Limit of Blank	< 1.5 µg/dL	0.457 µg/dL
AutoDELFIA Neonatal T4 Kit	Limit of Detection	Not available	0.99 µg/dL
AutoDELFIA Neonatal T4 Kit	Limit of Quantitation	Not available	1.61 µg/dL
AutoDELFIA Neonatal T4 Kit	Interference	Bilirubin at 20 mg/dL in has no significant effect on the assay.	Icteric (unconjugated bilirubin ≤ 342 µmol/L, equivalent to 20 mg/dL in serum, and conjugated bilirubin ≤ 237 µmol/L, equivalent to 20 mg/dL in serum) samples do not interfere with the assay. Lipemic samples (Intralipid[1] ≤ 15 mg/mL in serum) do not interfere with the assay. Added

[1] Intralipid is a registered trademark of Fresenius Kabi AB.

<table>
<tr><th>Predicate Device</th><th>FEATURE</th><th>Similarities (AutoDELFIA T4)</th><th>Differences (GSP T4)</th></tr>
<tr><td></td><td></td><td></td><td>hemoglobin up to 15 g/L does not interfere with the assay.</td></tr>
<tr><td>AutoDELFIA Neonatal T4 Kit</td><td>Cross reactivity</td><td>
<table>
<tr><th>Substance</th><th>Cross reactivity %</th></tr>
<tr><td>L-Thyroxine</td><td>100</td></tr>
<tr><td>3,3',5-Triiodo-L-thyronine (LT_3)</td><td>0.89</td></tr>
<tr><td>3,3',5-Triiodoacetic acid</td><td>0.45</td></tr>
<tr><td>3,5-Diiodo-L-thyronine</td><td>< 0.1</td></tr>
<tr><td>3,5-Diiodotyrosine (DIT)</td><td>< 0.1</td></tr>
<tr><td>5,5 Diphenylhydantoin</td><td>< 0.1</td></tr>
<tr><td>3-iodo-L-tyrosine (MIT)</td><td>< 0.1</td></tr>
<tr><td>Phenylbutazone</td><td>< 0.1</td></tr>
<tr><td>6-n-Propyl-2-thiouracil</td><td>< 0.1</td></tr>
<tr><td>Methimazole</td><td>< 0.1</td></tr>
<tr><td>L-Tyrosine</td><td>< 0.1</td></tr>
<tr><td>Acetylsalicylic acid</td><td>< 0.1</td></tr>
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<table>
<tr><th>Substance</th><th>Cross reactivity (%)</th></tr>
<tr><td>L-thyroxine</td><td>100</td></tr>
<tr><td>3,3´,5-Triiodo-L-thyronine (LT3)</td><td>1.67</td></tr>
<tr><td>3,3´,5-Triiodothyroacetic acid</td><td>0.14</td></tr>
<tr><td>3,5-Diiodo-L-thyronine</td><td>< 0.1</td></tr>
<tr><td>3,5-Diiodotyrosine (DIT) dihydrate</td><td>< 0.1</td></tr>
<tr><td>5,5-Diphenylhydantoin</td><td>< 0.1</td></tr>
<tr><td>3-iodo-L-tyrosine (MIT)</td><td>< 0.1</td></tr>
<tr><td>Phenylbutazone</td><td>< 0.1</td></tr>
<tr><td>6-n-Propyl-2-thiouracil</td><td>< 0.1</td></tr>
<tr><td>Methimazole</td><td>< 0.1</td></tr>
<tr><td>L-Tyrosine</td><td>< 0.1</td></tr>
<tr><td>Acetylsalicylic acid</td><td>< 0.01</td></tr>
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Wallac Oy
c/o Susan K. Hamann
Regulatory Affairs Manager
940 Winter Street
Waltham, MA, 02451

APR 2 2 2011

Re: k103484
Trade Name: GSP Neonatal Thyroxine (T4) kit
Regulation Number: 21 CFR §862.1700
Regulation Name: Total thyroxine test system.
Regulatory Class: Class II
Product Code: KLI
Dated: November 24, 2010
Received: February 24, 2011

Dear Ms. Hamann:

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 Parts 801 and 809), 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 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) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Courtney 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): __K103484_____

Device Name: **The GSP Neonatal Thyroxine (T4) kit (3302-001U)**

Indications for Use:

The GSP Neonatal Thyroxine (T4) kit is intended for the quantitative determination of human thyroxine (T4) in blood specimens dried on filter paper as an aid in screening newborns for congenital (neonatal) hypothyroidism using the GSP instrument.

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 OF NEEDED)

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

Carol C. Benson

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

510(k) K103484