1. Name, Address of Contact

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FDA Establishment No. 3050015
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Charles A. Peterson
CEO

Jason Reynolds
Official Correspondent

2. Name of the Device

Product Classification

Regulation Number:	21 CFR 862.2150
Classification Panel:	Clinical Chemistry
Product Code:	JJC
Product Code Name:	Analyzer, Chemistry (Sequential Multiple, Continuous Flow) Clinical Use
Device Classification:	Class I

Product Nomenclature

Common Name:	Continuous Flow Analyzer
Proprietary Name:	SPOTCHECK® Flow
Model Number(s):	350D Interface Unit; 307 Digital Photometer/Fluorometer; and NeoPac™ Software

3. Identification of the legally-marketed device for which substantial equivalence is claimed

The proposed devices are *new components* of Astoria-Pacific's FDA-cleared SPOTCHECK Analyzer system with associated 510(k) numbers k883020 and k851542.

4. Description of the Device

- Astoria-Pacific SPOTCHECK Flow (system marketed with new 307 detector)
- Astoria-Pacific SPOTCHECK Analyzer with NeoPac (Fluorometric and Photometric Detection options, i.e. predicate detectors)

Introduction

The SPOTCHECK continuous flow analyzer consists of various devices that interact together to provide a complete in vitro diagnostic (IVD) instrument system for use with Astoria-Pacific's neonatal screening assays. The technology can be considered automated bench chemistry in which continuously flowing reagents are mixed with the sample, ultimately producing a detectable product that correlates to analyte concentration. Proper conditions for reactions are controlled by using a variety of techniques such as specific timing for reagent inputs, incubation at specific temperatures, and/or dialysis. Depending upon the particular IVD assay, system components may differ slightly. In each case however, a system consists of an autosampler, a pump for reagents and sample streams, a module where assay chemistry occurs, a detector (including flowcell), and an interface unit that facilitates communication with the software.

The software, device modification, and new device described herein do not propose to alter the FDA-cleared assays used on the instrument.

Indications for use

The devices described herein do not contain any one specific indication for use, nor does the complete *generic* system for which they are a part. Complete systems are used to screen for inborn errors of metabolism in neonatal patient dried blood spots. Indications for use (**bold**), and the respective Astoria-Pacific reagent kits available are provided below:

SPOTCHECK Flow options

- **Galactose-1-phosphate uridyltransferase (GALT) enzyme deficiency (Galactosemia);** SPOTCHECK Uridyltransferase 50 Hour Reagent Kit
- **Galactose and galactose-1-phosphate, elevated total galactose concentration (Galactosemia);** SPOTCHECK Total Galactose 50 Hour Reagent Kit
- **Phenylalanine, elevated concentration (Phenylketonuria);** SPOTCHECK Phenylalanine 50 Hour Reagent Kit
- **Glucose-6-phosphate dehydrogenase enzyme deficiency;** SPOTCHECK G6PD 50 Hour Reagent Kit
- **Tyrosine, elevated concentration (Tyrosinemia);** SPOTCHECK Tyrosine 50 Hour Reagent Kit

SPOTCHECK Analyzer with NeoPac options

- **Galactose-1-phosphate uridyltransferase (GALT) enzyme deficiency (Galactosemia);** SPOTCHECK Uridyltransferase 50 Hour Reagent Kit
- **Biotinidase enzyme deficiency;** SPOTCHECK Biotinidase 50 Hour Reagent Kit
- **Galactose and galactose-1-phosphate, elevated total galactose concentration (Galactosemia);** SPOTCHECK Total Galactose 50 Hour Reagent Kit
- **Phenylalanine, elevated concentration (Phenylketonuria);** SPOTCHECK Phenylalanine 50 Hour Reagent Kit
- **Glucose-6-phosphate dehydrogenase enzyme deficiency;** SPOTCHECK G6PD 50 Hour Reagent Kit
- **Tyrosine, elevated concentration (Tyrosinemia);** SPOTCHECK Tyrosine 50 Hour Reagent Kit

Proposed Modifications

The proposed modifications to the analyzer system components allow for 2 new unique system options; they are as follows:

1. 350D Interface Unit: The predicate interface unit used for communications between detectors and software has been updated to accommodate the new software*.

OR

2. 307 Digital Photometer/Fluorometer: A new detector has been developed as an alternative to using the interface unit and predicate fluorometric detector. It is intended to be used with the new software*.

AND

*NeoPac: A new software package has been developed to replace outdated software. The 2 options listed above both depend on this software to complete the system.

Each new or modified component is briefly described below:

NeoPac Software

NeoPac is a newly developed software package designed to replace Astoria-Pacific's predicate software package. It is intended for use with new components and Microsoft® operating systems currently on the market. The software facilitates similar instrument controls as the predicate package, while adding minor but important functionality.

350D Interface Unit

The 350D facilitates electronic communication between NeoPac software and the detector(s), autosampler and pump. Each unit has 7 analog detector inputs on the front panel, a power cord connection, and cable connections for a PC, autosampler and pump. Its sole purpose is to provide a mechanism for commands and data to flow to and from the software and system components. The 350D is modified from the predicate device (350 Interface Unit) in order to communicate with new software.

307 Digital Photometer/Fluorometer

The 307 detector is a newly developed detection platform intended to provide an alternative option to the interface unit and one or more detectors in the SPOTCHECK analyzer system. Aside from providing a state-of-the-art option for detection, its spatial requirements are significantly less than the predicate device. It can be manufactured with up to 4 unique photometric or fluorometric detection channels and an additional analog input (offering the ability to connect to a standalone detector). In conjunction with NeoPac software, it facilitates the communication of data and commands between a PC, autosampler and pump.

The 307 consists of a base module with up to 4 detection channels (not including a reference channel); each channel is either a fluorometer module or a photometric subassembly. The fluorometer module is a removable device that contains a flowcell, excitation LED, and emission bandpass filter. Each fluorometer module is manufactured according to the specifications of the assay it is intended to be used with. The photometric subassembly is not removable by the user.

The only significant differences between the 307 and the predicate detectors (321 and 315) are the use of LEDs for excitation (fluorometry) and a bandpass filter instead of a monochromator (photometry).

Comparison of Devices Mentioned in the Submission

	Device			
510(k)	k101392		k883020	k851542
Original Name	n/a	n/a	RFA300	RFA300
Current Name	SPOTCHECK Flow	SPOTCHECK Analyzer with NeoPac	SPOTCHECK Analyzer	SPOTCHECK Analyzer
Software	NeoPac	NeoPac	FASPac	FASPac
Interface Unit	None	350D	350	350
Detector	307	321 and/or 315	321	315
Detection Method	Fluorometric (PMT)	Fluorometric (PMT) and/or Photometric (Monochromator)	Fluorometric (PMT)	Photometric (Monochromator)
Light Source	Ex. wavelength LED	Quartz-halogen	Quartz-halogen	Tungsten-halogen
Other system components (e.g. sampler, pump, chemistry cartridges)	Same	Same	Same	Same

5. Statement of Intended Use

The devices described herein are intended to be used with Astoria-Pacific's SPOTCHECK family of neonatal screening reagent kits. Assays currently offered on the system included Uridyltransferase (GALT), Biotinidase**, Total Galactose, Phenylalanine, G6PD, and Tyrosine. They are intended for use by qualified clinical laboratory professionals.

**Astoria-Pacific is not currently seeking FDA-clearance for Biotinidase on the SPOTCHECK Flow.

6. Device Comparison

EP9-A2 Study

The first study described below adhered to the protocol outlined in *Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline-Second Edition*, EP9-A2. The new system option including the 307 detector was directly compared against the appropriate detector (321 Fluorometer) for 5 neonatal screening assays currently on the market. Results are summarized in the table *Method Comparison and Bias Estimation Using New 307 Detector.*

Dried blood spots were obtained to represented both normal and deficient conditions for each of the 5 individual assays used on the SPOTCHECK system. Since patient samples with deficient and partially-deficient conditions are rare and especially difficult to obtain, in some cases dried blood spot controls provided by different manufacturers (including Astoria-Pacific and the Centers for Disease Control) were used to ensure adequate sample distribution across the assay range. Samples tested include responses around the medical decision levels for each individual assay. These levels were chosen using the cut-offs established in Astoria-Pacific's quality control laboratory.

The results of the EP9-A2 protocol demonstrate that there is no clinically-significant bias which would suggest a need for further analysis. The fluorometric assays performed nearly identical on both the 307 and predicate detector. Since the detection paradigms on the 307 are equivalent to the predicate device, the strong agreement was anticipated.

Method Comparison and Bias Estimation Using New 307 Detector					
Parameter	SPOTCHECK Assay Tested				
	Total Galactose	UT (GALT)	Phenylalanine	G6PD	Tyrosine
Units	mg/dl	µM NADH	mg/dl	µM NADH	mg/dl
Linear Regression slope (m), intercept (b)	m = 1.02 b = -0.58	m = 0.96 b = -1.49	m = 1.01 b = -0.02	m = 1.00 b = -1.24	m = 1.01 b = -0.05
Correlation Coefficient, R^2	1.00	0.99	1.00	1.00	1.00
Number of Samples (N)	69	58	70	60	71
Replicates per Sample	2	2	2	2	2
Medical Decision Level, X_c	10	60	4	40	4
Bias at X_c	-0.3	-3.8	0.02	-1.1	0.01
95% Confidence Interval of Bias at X_c	9.6 to 9.7	55 to 57	4.0 to 4.0	39 to 39	4.0 to 4.0
Acceptable Bias Near X_c	9.4 to 10.6	56 to 64	3.7 to 4.3	37 to 43	3.8 to 4.2

Additional Study of Newborn Specimens

A second comparison study for each assay (Uridyltransferase (GALT), Total Galactose, Phenylalanine, and Tyrosine) was performed using a minimum of 88 newborn dried blood spots obtained from domestic newborn screening laboratories. The new G6PD study involved 50 newborn specimens, however the original study (described above) utilized a significant number of newborn specimens. The results of the G6PD study include 42 measurements from the previous study.

The results from the second study closely match the original study and no clinically significant bias between detection paradigms was observed.

Assay	N =	No. of Newborns	Slope	95% Confidence (Upper, Lower)	Intercept	95% Confidence (Upper, Lower)	R^2
Total Galactose	112	96	0.99	0.98, 1.01	-0.83	-0.73, -0.93	0.99
Phenylalanine	112	96	0.99	0.98, 0.99	0.01	0.0, 0.02	1.00
Tyrosine	101	88	0.99	0.98, 0.99	0.01	0.0, 0.02	1.00
UT (GALT)	96	94	1.03	1.00, 1.07	-7.6	-3.3, -12.0	0.97
G6PD	92	92	0.97	0.96, 0.98	-0.56	-1.4, 0.28	1.00

Sensitivity

Evaluation of TGal, Phe, Tyr, and G6PD utilized 3 low-level samples analyzed over 3 days in batches of 20 low-level replicates and 20 blank replicates per run (for each method). Evaluation of GALT utilized 2 low-level samples analyzed over 3 days in batches of 20 low-level replicates and 20 blank replicates per run (1 low level sample was used in 2 of 3 runs, 40 replicates in total). Results were used to determine the sensitivity of the analytical system for each method. The study was conducted according to *CLSI EP17-A: Protocols for Determination of Limits of Detection and Limits of Quantitation; Approved Guideline*. The study results demonstrated equivalent or improved sensitivity performance when compared to the predicate system. A summary is provided below.

	307/NeoPac LoD	Predicate Device LoD
TGal	0.2 mg/dl	0.3 mg/dl
Phe	0.1 mg/dl	0.2 mg/dl
Tyr	0.2 mg/dl	0.2 mg/dl
GALT	3 µM NADPH	5 µM NADPH
G6PD	1 µM NADPH	2 µM NADPH

Precision

Evaluation of precision for TGal, Phe, Tyr and GALT utilized 3 samples at different levels of activity or concentration (generally: low, medium, and high) for each method tested. Samples were analyzed over 5 days, 1 run per day, 8 replicates of each sample per run. Sample order was changed for each run.

Evaluation of precision for G6PD also utilized 3 samples at low, medium and high activity, however, samples were analyzed over 4 days with 1 run per day for 3 days and 2 runs on one day. Eight replicates of each sample were analyzed per run in order to attain the degrees of freedom recommended in the protocol. Sample order was the same for each run. The study was conducted according to CLSI EP5-A2: *Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline – Second Edition.*

Each method's results demonstrated an improvement in precision over the predicate device at comparable levels of analyte/enzyme activity. The only exception is an observed increase in imprecision at very low levels of G6PD enzyme activity, however, said imprecision is acceptable and not clinically significant. Neither within-run nor total precision suggests that a neonate with deficient G6PD activity would be qualified as normal, especially considering the comparable precision around the clinical decision level.

TGal – 307/NeoPac	Normal	Near Cutoff	Galactosemic
n (# of observations)	40	40	40
Mean (mg/dL)	6.2	11.3	31.4
S_r (within-run precision)	0.051	0.118	0.168
C.V. (within-run)	0.82	1.05	0.53
B (daily mean precision)	0.208	0.144	0.609
S_T (total precision)	0.214	0.181	0.629
%C.V. (total)	3.4	1.6	2.0

TGal – Predicate Device	Normal	Normal	Galactosemic
n (# of observations)	20	20	20
Mean (mg/dL)	7.75	5.82	29.3
S_r (within-run precision)	0.340		
C.V. (within-run)	4.30		
S_T (total precision)		0.60	2.20
%C.V. (total)		10.3	7.5

NOTE: Cells in gray signify unavailable data for the predicate device.

Phe – 307/NeoPac	Normal	Near Cutoff	Elevated
n (# of observations)	40	40	40
Mean (mg/dL)	2.0	4.5	15.3
S_r (within-run precision)	0.014	0.028	0.065
C.V. (within-run)	0.70	0.63	0.42
B (daily mean precision)	0.064	0.099	0.152
S_T (total precision)	0.065	0.102	0.163
%C.V. (total)	3.3	2.3	1.1

Precision results (continued)

Phe – Predicate Device	Normal	Near Cutoff	Elevated
n (# of observations)	20	20	20
Mean (mg/dL)	2.89	5	9.99
S_r (within-run precision)		0.210	
C.V. (within-run)		4.20	
S_T (total precision)	0.27		0.86
%C.V. (total)	9.4		8.6

Tyr - 307/NeoPac	Normal	Near Cutoff	Tyrosinemic
n (# of observations)	40	40	40
Mean (mg/dL)	1.8	7.7	18.5
S_r (within-run precision)	0.036	0.061	0.177
C.V. (within-run)	1.99	0.79	0.96
B (daily mean precision)	0.070	0.178	0.762
S_T (total precision)	0.078	0.187	0.780
%C.V. (total)	4.3	2.4	4.2

Tyr - Predicate Device	Near Cutoff	Near Cutoff
n (# of observations)	30	30
Mean (mg/dL)	6.04	8.52
S_r (within-run precision)	0.10	0.35
C.V. (within-run)	1.60	4.10
S_T (total precision)	0.16	0.42
%C.V. (total)	2.8	5.0

GALT - 307/NeoPac	Galactosemic	Carrier	Normal
n (# of observations)	40	40	40
Mean (µM NADPH)	6.6	62.5	122.0
S_r (within-run precision)	0.34	1.05	1.21
C.V. (within-run)	5.18	1.67	0.99
B (daily mean precision)	0.28	2.68	4.37
S_T (total precision)	0.43	2.86	4.51
%C.V. (total)	6.5	4.6	3.7

GALT - Predicate Device	Near Cutoff	Normal
n (# of observations)	96	58
Mean (µM NADPH)	30	235
S_r (within-run precision)	2.95	12.60
C.V. (within-run)	9.9	5.3
S_T (total precision)	3.7	13.0
%C.V. (total)	13	5.5

Precision results (continued)

G6PD - 307/NeoPac	Deficient	Near Cutoff	Normal
n (# of observations)	40	40	40
Mean (µM NADPH)	3.4	39.7	83.1
S_r (within-run precision)	0.28	0.53	1.18
C.V. (within-run)	8.15	1.33	1.42
B (daily mean precision)	0.15	1.98	5.29
S_T (total precision)	0.30	2.04	5.40
%C.V. (total)	8.7	5.1	6.5

G6PD - Predicate Device	Deficient	Near Cutoff	Normal
n (# of observations)	16	16	16
Mean (µM NADPH)	7.8	43	158
S_r (within-run precision)	0.25	1.9	4.9
C.V. (within-run)	3.2	4.4	3.1
S_T (total precision)	0.4	2.6	13.7
%C.V. (total)	5.4	6.0	8.7

7. Overall Conclusion

Device comparison for the assays of interest demonstrates strong agreement. Astoria-Pacific concludes that the new system options are safe and effective, and equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

FEB 04 2011

Astoria-Pacific, Inc.
c/o Jason Reynolds
Director of Research and Development
15130 S.E. 82nd Drive
Clackamas, OR 97015

Re: k101392
Trade/Device Name: Astoria-Pacific SPOTCHECK Flow, Astoria-Pacific SPOTCHECK Analyzer with NeoPac, Fluorometer and Photometer, Astoria-Pacific SPOTCHECK Analyzer with NeoPac and Photometer, Astoria-Pacific SPOTCHECK Analyzer with NeoPac and Fluorometer
Regulation Number: 21 CFR § 862.1315
Regulation Name: Galactose-1-phosphate uridyl transferase test system
Regulatory Class: Class II
Product Code: KQP, JIA, JNB, JBL, CDR, NAK, JJC
Dated: December 29, 2010
Received: December 30, 2010

Dear Mr. Reynolds:

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

510(k): k101392

Device Name: Astoria-Pacific SPOTCHECK® Flow™

Indications For Use:

The SPOTCHECK Flow system is used for *in vitro* diagnostic newborn screening in conjunction with Astoria-Pacific's SPOTCHECK family of reagent kits. The specific inborn errors in metabolism screened for (**bold**), and the respective Astoria-Pacific dried blood spot assays are:

- **Galactose-1-phosphate uridyltransferase (GALT) enzyme deficiency (Galactosemia);** SPOTCHECK Uridyltransferase 50 Hour Reagent Kit
- **Galactose and galactose-1-phosphate, elevated total galactose concentration (Galactosemia);** SPOTCHECK Total Galactose 50 Hour Reagent Kit
- **Phenylalanine, elevated concentration (Phenylketonuria);** SPOTCHECK Phenylalanine 50 Hour Reagent Kit
- **Glucose-6-phosphate dehydrogenase enzyme deficiency;** SPOTCHECK G6PD 50 Hour Reagent Kit
- **Tyrosine, elevated concentration (Tyrosinemia);** SPOTCHECK Tyrosine 50 Hour Reagent Kit

The system is intended for screening use only and is not intended for monitoring purposes.

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 Benson

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

Indications For Use

510(k): k101392

Device Name: Astoria-Pacific SPOTCHECK® Analyzer with NeoPac™, Fluorometer and Photometer

Indications For Use:

The SPOTCHECK Analyzer system is used for *in vitro* diagnostic newborn screening in conjunction with Astoria-Pacific's SPOTCHECK family of reagent kits. The specific inborn errors in metabolism screened for **(bold)**, and the respective Astoria-Pacific dried blood spot assays are:

- **Galactose-1-phosphate uridyltransferase (GALT) enzyme deficiency (Galactosemia);** SPOTCHECK Uridyltransferase 50 Hour Reagent Kit
- **Biotinidase enzyme deficiency;** SPOTCHECK Biotinidase 50 Hour Reagent Kit
- **Galactose and galactose-1-phosphate, elevated total galactose concentration (Galactosemia);** SPOTCHECK Total Galactose 50 Hour Reagent Kit
- **Phenylalanine, elevated concentration (Phenylketonuria);** SPOTCHECK Phenylalanine 50 Hour Reagent Kit
- **Glucose-6-phosphate dehydrogenase enzyme deficiency;** SPOTCHECK G6PD 50 Hour Reagent Kit
- **Tyrosine, elevated concentration (Tyrosinemia);** SPOTCHECK Tyrosine 50 Hour Reagent Kit

The system is intended for screening use only and is not intended for monitoring purposes.

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

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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

Indications For Use

510(k): k101392

Device Name: Astoria-Pacific SPOTCHECK® Analyzer with NeoPac™ and Photometer

Indications For Use:

The SPOTCHECK Analyzer system is used for *in vitro* diagnostic newborn screening in conjunction with Astoria-Pacific's SPOTCHECK family of reagent kits. The specific inborn error in metabolism screened for (**bold**), and the respective Astoria-Pacific dried blood spot assay are:

- **Biotinidase enzyme deficiency;** SPOTCHECK Biotinidase 50 Hour Reagent Kit

The system is intended for screening use only and is not intended for monitoring purposes.

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

Indications For Use

510(k): k101392

Device Name: Astoria-Pacific SPOTCHECK® Analyzer with NeoPac™ and Fluorometer

Indications For Use:

The SPOTCHECK Analyzer system is used for *in vitro* diagnostic newborn screening in conjunction with Astoria-Pacific's SPOTCHECK family of reagent kits. The specific inborn errors in metabolism screened for (**bold**), and the respective Astoria-Pacific dried blood spot assays are:

- **Galactose-1-phosphate uridyltransferase (GALT) enzyme deficiency (Galactosemia);** SPOTCHECK Uridyltransferase 50 Hour Reagent Kit
- **Galactose and galactose-1-phosphate, elevated total galactose concentration (Galactosemia);** SPOTCHECK Total Galactose 50 Hour Reagent Kit
- **Phenylalanine, elevated concentration (Phenylketonuria);** SPOTCHECK Phenylalanine 50 Hour Reagent Kit
- **Glucose-6-phosphate dehydrogenase enzyme deficiency;** SPOTCHECK G6PD 50 Hour Reagent Kit
- **Tyrosine, elevated concentration (Tyrosinemia);** SPOTCHECK Tyrosine 50 Hour Reagent Kit

The system is intended for screening use only and is not intended for monitoring purposes.

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

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