AUG 2 3 2010

510(k) SUMMARY

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

The assigned 510(k) number is K093916

Date: August 18, 2010

Submitted by: Wallac Oy
a subsidiary of PerkinElmer
Mustionkatu 6
20750 Turku, Finland

Contact person:
Primary: Kay A. Taylor
Tele: 317-418-1735
Fax: 317-536-3064

Secondary: Susan Hamann
Tele: 781-633-5872
Fax: 781-633-5983

Trade Name: NeoBase Non-derivatized MSMS Kit

Common Name: NeoBase kit or Non-derivatized kit

Classification Name: Newborn screening test system for amino acids, free carnitine, and acylcarnitines using tandem mass spectrometry (21 CFR § 862.1055 /Product code NQL)

Predicate device(s): NeoBase Non-derivatized MSMS Kit, K083130

Device description: The measurement of amino acids, succinylacetone, free carnitine, and acylcarnitines with the NeoBase assay involves extraction of dried blood spots from newborns with a solution containing stable-isotope labeled internal standards and analysis using a tandem mass spectrometry (MSMS) system. The response of each analyte relative to their corresponding stable-isotope labeled internal standard is proportional to analyte concentration

Intended Use: Indications for Use

The Neobase Non-derivatized MSMS reagent kit (for use on the PerkinElmer TQD MSMS Screening System) is intended for the measurement and evaluation of amino acids, succinylacetone, free carnitine, and acylcarnitine concentrations from newborn heel prick blood samples dried on filter paper.

Quantitative analysis of these analytes (Table 1) and their relationship with each other is intended to provide analyte concentration profiles that may aid in screening newborns for metabolic disorders.

Instruments:
- PerkinElmer MS2 Tandem Mass Spectrometer System (MS2)
- PerkinElmer MSMS Quattro Micro (Qmicro) Newborn Screening System
- PerkinElmer MSMS TQD Newborn Screening System

Table 1. Analytes measured by the NeoBase Non-derivatized MSMS Kit.

ANALYTE NAME	ABBREVIATION
Amino acids	
Alanine	Ala
Arginine	Arg
Citrulline	Cit
Glycine	Gly
Leucine/Isoleucine/Hydroxyproline*	Leu/Ile/Pro-OH
Methionine	Met
Ornithine	Orn
Phenylalanine	Phe
Proline	Pro
Tyrosine	Tyr
Valine	Val
Carnitines	
Free carnitine	C0
Acetylcarnitine	C2
Propionylcarnitine	C3
Malonylcarnitine / 3-Hydroxy-butyrylcarnitine*	C3DC/C4OH
Butyrylcarnitine	C4
Methylmalonyl / 3-Hydroxy-isovalerylcarnitine*	C4DC/C5OH
Isovalerylcarnitine	C5
Tiglylcarnitine	C5:1
Glutarylcarnitine / 3-Hydroxy-hexanoylcarnitine*	C5DC/C6OH
Hexanoylcarnitine	C6
Adipylcarnitine	C6DC
Octanoylcarnitine	C8

Octenoylcarnitine	C8:1
Decanoylcarnitine	C10
Decenoylcarnitine	C10:1
Decadienoylcarnitine	C10:2
Dodecanoylcarnitine	C12
ANALYTE NAME	ABBREVIATION
Carnitines	
Dodecenoylcarnitine	C12:1
Tetradecanoylcarnitine (Myristoylcarnitine)	C14
Tetradecenoylcarnitine	C14:1
Tetradecadienoylcarnitine	C14:2
3-Hydroxy-tetradecanoylcarnitine	C14OH
Hexadecanoylcarnitine (palmitoylcarnitine)	C16
Hexadecenoylcarnitine	C16:1
3-Hydroxy-hexadecanoylcarnitine	C16OH
3-Hydroxy-hexadecenoylcarnitine	C16:1OH
Octadecanoylcarnitine (Stearoylcarnitine)	C18
Octadecenoylcarnitine (Oleylcarnitine)	C18:1
Octadecadienoylcarnitine (Linoleylcarnitine)	C18:2
3-Hydroxy-octadecanoylcarnitine	C18OH
3-Hydroxy-octadecenoylcarnitine	C18:1OH
Ketones	
Succinylacetone	SA

*Analytes in these rows are either isomers or isobars and cannot be distinguished in the tandem mass spectrometry experiment.

Device Comparison:

Table 5.1: Comparison of the modified device (NeoBase Non-derivatized MSMS Assay on the TQD Platform_ and predicate device.

GENERAL CHARACTERISTICS		
Parameter	**Modified Device**	**Predicate Device**
Intended Use	The NeoBase Non-derivatized MSMS reagent kit is intended for the measurement and evaluation of amino acids, succinylacetone, free carnitine, and acylcarnitine concentrations from newborn heel prick blood samples dried on filter paper. Quantitative analysis of these analytes (Table 1) and their relationship with each other is intended to provide analyte concentration profiles that may aid in screening newborns for metabolic disorders. *(intended use employs a table to identify each analyte detected)*	Same
Instrumentation	PerkinElmer MS2 Tandem Mass Spectrometer System (MS2) PerkinElmer MSMS Quattro Micro (Qmicro)	- PerkinElmer MS2 Tandem Mass Spectrometer System - PerkinElmer MS/MS Qmicro

	Newborn Screening System PerkinElmer MSMS TQD Newborn Screening System	Screening System

GENERAL CHARACTERISTICS		
Parameter	**Modified Device**	**Predicate Device**
Disorders Screened	Amino-, organic-, and fatty acid metabolic disorders	Same
Analytes Measured	Amino acids, free carnitine, acylcarnitines, and succinylacetone	Same
Methodology	Microplate based tandem mass spectrometric assay	Same
Test Principle	Amino acids and carnitines in sample are measured by tandem mass spectrometry through analyte-specific mass transitions appropriate for each type of analyte. The extracted analytes are measured for set time periods and compared to the signal intensities produced by the corresponding isotope-labeled internal standards. The concentrations are determined by comparing the signal intensities of the known standards to the measured analytes.	Same
Quantitative Nature	Quantitative by internal standardization	Same
Sample Requirements	Newborn blood collected on Schleicher and Schuell 903 filter paper per NCCLS standards	Same
Throughput	Ninety-six tests per microtiter plate. Multiple plates can be analyzed	Same
Analysis Time	2 to 2.5 hours per plate.	Same
Controls	Controls are blood spots from processed human blood enriched with several amino acids, carnitines and succinylacetone.	Same
Calibrators	Internal calibration using several isotopically labeled standards, included as dried material in vials. Internal standards must be reconstituted with extraction solution prior to their use.	Same
Assay format	Non-derivatized (analytes measured in their native forms)	Same

Analytes measured by the device

Table 5.2: Analytes measured by the NeoBase kit and their most common abbreviated names

ANALYTE NAME	ABBREVIATION
Amino acids	
Alanine	Ala
Arginine	Arg
Citrulline	Cit
Glycine	Gly
Leucine/Isoleucine/Hydroxyproline*	Leu/Ile/Pro-OH
Methionine	Met

Ornithine	Orn
Phenylalanine	Phe
Proline	Pro
Tyrosine	Tyr
Valine	Val
Carnitines	
Free carnitine	C0
Acetylcarnitine	C2
Propionylcarnitine	C3
Malonylcarnitine / 3-Hydroxy-butyrylcarnitine*	C3DC/C4OH
Butyrylcarnitine	C4
Methylmalonyl / 3-Hydroxy-isovalerylcarnitine*	C4DC/C5OH
Isovalerylcarnitine	C5
Tiglylcarnitine	C5:1
Glutarylcarnitine / 3-Hydroxy-hexanoylcarnitine*	C5DC/C6OH
Hexanoylcarnitine	C6
Adipylcarnitine	C6DC
Octanoylcarnitine	C8
Octenoylcarnitine	C8:1
Decanoylcarnitine	C10
Decenoylcarnitine	C10:1
Decadienoylcarnitine	C10:2
Dodecanoylcarnitine	C12
Dodecenoylcarnitine	C12:1
Tetradecanoylcarnitine (Myristoylcarnitine)	C14
Tetradecenoylcarnitine	C14:1
Tetradecadienoylcarnitine	C14:2
3-Hydroxy-tetradecanoylcarnitine	C14OH
Hexadecanoylcarnitine (palmitoylcarnitine)	C16
Hexadecenoylcarnitine	C16:1
3-Hydroxy-hexadecanoylcarnitine	C16OH
3-Hydroxy-hexadecenoylcarnitine	C16:1OH
Octadecanoylcarnitine (Stearoylcarnitine)	C18
Octadecenoylcarnitine (Oleylcarnitine)	C18:1
Octadecadienoylcarnitine (Linoleylcarnitine)	C18:2
3-Hydroxy-octadecanoylcarnitine	C18OH
3-Hydroxy-octadecenoylcarnitine	C18:1OH
Ketones	
Succinylacetone	SA or SUAC

*Analytes in these rows are either isomers or isobars and cannot be distinguished in the tandem mass spectrometry experiment.

Substantial equivalency:

(1) Non-clinical

The performance of the NeoBase Non-derivatized MSMS kit on the PerkinElmer TQD Triple Quadrupole Mass Spectrometer System (PerkinElmer TQD platform) was compared to the predicate MS^2 and PerkinElmer Quattro Micro platforms performance, K031878. All of these are tandem mass spectrometry platforms capable of measuring the NeoBase panel of amino acids and acylcarnitines from neonatal dried blood spots. The panel of analytes measured by all three platforms is the same. Analytically, all devices are identical regarding sample

requirements, sample processing, analysis time and assay format (Tables 5.1 and 5.2).

The performance of the NeoBase kit on the PerkinElmer TQD platform was compared against the corresponding characteristics reported in the predicate device product insert. A summary of the performance characteristics is presented in Tables 5.3 to 5.6. The NeoBase kit provides equivalent precision, recoveries and measurable ranges that cover all clinically significant ranges on all platforms tested. Therefore, the NeoBase kit provides performance levels that are adequate for its intended use on the MS^2, PerkinElmer Quattro Micro and PerkinElmer TQD platforms

Precision

Table 5.3: Averaged Total imprecision for amino acids. Data shown are average Total imprecision coefficients of variation (%CV) for each platform.

Assay	ALA	ARG	CIT	GLY	LEU	MET	ORN	PHE	SA	TYR	VAL
QM	9	7	8	10	7	8	13	7	10	7	8
MS^2	10	9	9	14	10	15	10	9	13	8	9
TQD	10	10	11	11	10	11	11	10	18	11	12

Table 5.4: Averaged Total imprecision for carnitine and acylcarnitines. Data shown are average Total imprecision coefficients of variation (%CV) for each platform.

Assay	C0	C2	C3	C4	C5	C5DC	C6	C8	C10	C12	C14	C16	C18
QM	9	9	9	9	10	11	10	10	10	9	9	10	10
MS^2	9	9	9	9	10	10	15	9	9	9	10	10	9
TQD	9	13	11	11	12	11	11	13	11	11	11	11	11

Recovery

Table 5.5: Averaged analyte percent recovery and recovery ranges for all platforms

	Mean % Recovery			Recovery SD, %			95% Confidence interval		
Analyte	TQD	QMicro	MS^2	TQD	QMicro	MS^2	TQD	QMicro	MS^2
ALA	100	92	83	7	12	10	85-115	69-116	63-104
ARG	86	87	87	7	8	7	72-100	72-102	73-100
CIT	93	96	95	6	7	11	82-104	83-109	73-116
GLY	90	93	86	19	12	17	51-128	69-117	51-120
LEU	101	93	88	14	10	8	73-128	72-113	72-103
MET	97	88	86	6	6	6	85-110	75-101	73-98
ORN	98	91	91	10	8	6	78-117	75-108	78-103
PHE	94	95	89	8	7	6	78-109	81-109	76-101
PRO	97	93	84	6	8	8	84-110	78-108	68-100
SA	57	64	62	6	6	7	44-70	52-77	48-76
TYR	84	96	102	6	9	10	72-95	79-114	81-122
VAL	90	88	78	9	9	10	72-109	69-106	58-97
C0	104	91	107	5	11	14	95-114	70-112	80-134

C2	95	93	97	7	7	8	82-108	79-108	80-113
C3	93	94	95	4	8	10	85-102	78-110	76-115
C4	93	91	92	4	9	14	85-101	72-109	64-121
C5	86	91	94	5	7	10	75-97	78-105	74-114
C5DC	99	99	104	4	8	8	90-107	83-115	87-121
C6	91	91	83	6	5	10	80-103	82-101	63-103
C8	100	90	96	8	11	13	84-117	68-113	70-121
C10	92	97	95	3	5	9	85-99	86-108	78-112
C12	102	93	103	5	9	14	93-111	75-112	75-130
C14	92	92	94	6	5	6	81-104	82-102	81-107
C16	92	93	84	5	13	15	83-101	68-118	55-114
C18	89	91	94	10	7	13	70-109	77-105	69-119

Measurable Ranges

Table 5.6: Measurable ranges for both assays and corresponding clinically significant ranges (all in µM/L).

Analyte	**TQD Range (µM)**		**QMicro Range (µM)**		**MS² Range (µM)**		**Cutoff Range (µM)**
	Lower	Upper	Lower	Upper	Lower	Upper	
Ala	452	4841	387	4090	444	4203	975–1625
Arg	27	4140	25	3721	27	3806	180–300
Cit	28	1716	27	1683	26	1655	113–188
Gly	309	4350	334	4487	365	4504	975–1625
Leu	266	2992	218	2545	219	2463	263–438
Met	31	1252	30	1185	28	1100	120–200
Orn	110	3914	115	3771	110	3645	360–600
Phe	79	2607	71	2341	73	2169	225–375
Pro	248	3735	251	3659	238	3327	450–750
SA	0.6	164.9	0.4	158.1	0.4	155.0	4–7.0
Tyr	75	2980	72	2816	75	2857	578–963
Val	197	2300	205	2358	176	1902	300–500
C0	51	2930	42	2274	43	2386	90–150
C2	35	743	35	735	37	745	128–213
C3	3.3	96	3.1	88	3.2	94	9.75–16.25
C4	0.20	70.8	0.14	59.8	0.13	57	2.25–3.75
C5	0.20	62.9	0.18	59.1	0.17	59.9	1.88–3.13
C5DC	0.18	32.6	0.13	28.9	0.10	29.2	0.6–1
C6	0.03	67.6	0.03	61.5	0.03	66.6	0.98–1.63
C8	0.05	39.8	0.04	35.2	0.04	35.8	1.2–2
C10	0.07	29.8	0.07	28.9	0.06	27.9	1.35–2.25
C12	0.05	50.8	0.05	42.7	0.05	41.7	1.88–3.13
C14	0.1	42.7	0.1	41.8	0.1	42.3	1.5–2.5
C16	2.3	90.5	2.8	107.3	2.9	106.7	11.25–18.75

C18	2.2	34	2.1	32	2	32	3–5.0

Method Correlation

An additional measure of the equivalency in the results obtained when the assay is executed using three platforms is the comparison of the actual measured concentrations for each of the analytes included in dried blood spots enriched with the analytes of interest. The raw data was matched per run per level for two comparisons: 1) MS^2 to PerkinElmer TQD; and 2) PerkinElmer Q Micro to TQD. Means were calculated per run per analyte per spiked level, to result in 25 means per platform for each analyte (5 levels times 5 runs per analyte). The results were averaged over the five spiked levels and the ratios of the means (per analyte) were then determined for the two comparisons (MS^2/TQD and Q Micro/TQD). If the two platforms being compared give equivalent concentration measurements, then the ratio will be 1.0. The mean ratio (averaged over five levels) of each analyte is presented in Tables 5.7 and 5.8 for the MS^2/TQD and Q Micro/TQD comparisons, respectively.

Table 5.7: Mean ratio of measured concentration for MS^2/TQD comparison. Mean ratios of 25 measurements shown along with corresponding SD, %CV, and upper and lower 95% confidence limits.

		ALA	ARG	CIT	GLY	LEU	MET	ORN	PHE	
MS^2/TQD	Mean	1.09	1.01	0.93	1.04	0.98	0.98	0.99	0.89	
	SD	0.07	0.02	0.03	0.07	0.03	0.03	0.02	0.03	
	% CV	6	2	3	7	3	3	2	3	
	LCL	0.96	0.96	0.86	0.90	0.92	0.92	0.94	0.83	
	UCL	1.22	1.05	0.99	1.17	1.04	1.05	1.04	0.95	
		PRO	SA	TYR	VAL	C0	C2	C3	C4	
	Mean	0.94	1.08	1.01	1.08	0.98	0.99	1.04	0.92	
	SD	0.03	0.05	0.03	0.06	0.03	0.03	0.03	0.03	
	% CV	3	5	3	6	3	3	3	3	
	LCL	0.87	0.98	0.95	0.96	0.92	0.92	0.98	0.86	
	UCL	1.00	1.17	1.06	1.19	1.05	1.05	1.10	0.98	
		C5	C5DC	C6	C8	C10	C12	C14	C16	C18
	Mean	0.92	0.97	0.89	0.97	0.94	0.98	1.01	0.99	0.99
	SD	0.03	0.04	0.03	0.04	0.03	0.04	0.04	0.03	0.04
	% CV	3	4	4	4	3	4	4	3	4
	LCL	0.85	0.88	0.82	0.90	0.87	0.89	0.94	0.93	0.92
	UCL	0.99	1.06	0.96	1.04	1.00	1.06	1.09	1.06	1.06

Table 5.8: Mean ratio of measured concentration for Q Micro/TQD comparison. Mean ratios of 25 measurements shown along with corresponding SD, %CV, and upper and lower 95% confidence limits.

		ALA	ARG	CIT	GLY	LEU	MET	ORN	PHE
Micro/TQ	Mean	0.92	1.00	1.00	0.98	1.01	1.08	1.06	0.97
	SD	0.04	0.05	0.06	0.05	0.06	0.04	0.04	0.06

	% CV	4	5	6	5	6	4	4	6
	LCL	0.84	0.90	0.87	0.88	0.90	1.00	0.98	0.84
	UCL	0.99	1.11	1.13	1.07	1.12	1.16	1.14	1.09
		PRO	SA	TYR	VAL	C0	C2	C3	C4
	Mean	1.02	1.04	1.00	1.08	0.99	0.94	0.95	1.03
	SD	0.03	0.04	0.05	0.07	0.03	0.04	0.04	0.04
	% CV	3	4	5	7	3	4	4	4
	LCL	0.95	0.96	0.91	0.95	0.93	0.86	0.87	0.96
	UCL	1.09	1.13	1.10	1.21	1.05	1.02	1.04	1.10
		C5	C5DC	C6	C8	C10	C12	C14	C16	C18
	Mean	0.97	0.97	1.00	1.00	0.98	1.02	1.00	1.00	1.02
	SD	0.03	0.03	0.03	0.03	0.03	0.03	0.04	0.04	0.04
	% CV	3	3	3	3	3	3	4	4	4
	LCL	0.91	0.91	0.93	0.94	0.92	0.96	0.93	0.93	0.95
	UCL	1.03	1.03	1.07	1.07	1.05	1.09	1.07	1.08	1.10

The ratios range from 0.89 to 1.09 for the MS^2/TQD comparison. Taking into account the small variation, the results indicate these two platforms give statistically equivalent results. Likewise, the ratios range from 0.92 to 1.08 for the Q Micro/TQD comparison and noting the small variation in the mean ratios, the results indicate these two platforms give statistically equivalent results.

(2) Clinical

CLINICAL CORRELATION STUDIES

The clinical correlation studies involved the analysis of 2499 random newborn screening specimens and 17 specimens with true positive diagnoses. In addition, a set of enriched samples (five levels) was analyzed (as singlicates of each level) for 16 runs to provide a total of 80 individual measurements. All samples were evaluated in parallel on the TQD and the predicate MS^2 platforms using the NeoBase kit. Clinical correlation was established by assessing whether or not the platforms were concordant in determining the paired samples to have analyte concentration values above or below their corresponding cutoffs. Examination on the number of concordant pairs for each analyte (cases in which both methods agreed) provided the percent agreements shown in Table 5.9.

Table 5.9: Percent agreement in clinical determinations between the TQD and MS^2 platforms.

Analyte	Total # of observations	% agreement	Analyte	Total # of observations	% agreement
ALA	2598	99.6%	C14	2598	99.9%
ARG	2598	99.9%	C16	2598	99.6%
CIT	2598	99.8%	C18	2598	99.9%
GLY	2598	99.5%	C4OH/C3DC	2518*	99.9%
LEU	2598	99.6%	C5OH/C4DC	2518*	99.9%
MET	2598	100.0%	C5:1	2518*	99.4%

ORN	2598	99.6%	**C6DC**	2518*	99.8%
PHE	2598	99.9%	**C8:1**	2518*	99.9%
PRO	2598	99.8%	**C10:1**	2518*	100.0%
SA	2598	99.5%	**C10:2**	2518*	99.7%
TYR	2598	99.2%	**C12:1**	2518*	100.0%
VAL	2598	99.7%	**C14-OH**	2518*	99.7%
C0	2598	100.0%	**C14:1**	2518*	99.8%
C2	2598	99.9%	**C14:2**	2518*	99.8%
C3	2598	100.0%	**C16-OH**	2518*	99.8%
C4	2598	99.9%	**C16:1**	2518*	99.9%
C5	2598	99.9%	**C16:1-OH**	2518*	99.8%
C5DC	2598	99.7%	**C18-OH**	2518*	99.6%
C6	2598	99.7%	**C18:1**	2518*	99.9%
C8	2598	99.8%	**C18:1-OH**	2518*	99.2%
C10	2598	99.9%	**C18:2**	2518*	100.0%
C12	2598	99.8%			

* For these analytes, newborn screening samples (presumptive negative data set, n=2499) and true positives (n=19, include the newly acquired NKH and H-ALA samples) were used.

COMPARISON OF TRUE POSITIVE SAMPLE RESULTS BETWEEN PLATFORM

The correlation between the test and predicate platforms included 17 samples with true positive diagnoses representing 14 disorders (Table 5.10). All of these cases were successfully detected by both platforms for 100% agreement in the clinical determination (Table 5.10).

Table 5.10: Summary of the analysis of true Positive samples by the NeoBase assay when performed on the MS^2 and TQD platforms

Sample	Disorder	Cases Detected		Elevated Analytes Detected by each Platform	
		TQD	Sciex	TQD	Sciex
1	TYR I	yes	yes	SA, TYR	SA, TYR
2	CPT II	yes	yes	C12, C14, C16, C16:1, C16:1 OH, C16-OH, C18, C18:1, C18:1-OH	C14, C14:OH, C16, C16:1, C16:1 OH, C16-OH, C18, C18:1, C18:1-OH, C18-OH
3	MMA	yes	yes	C3, C6,	C3
4	HMG	yes	yes	C5OH/C4DC, C6DC	C5OH/C4DC
5	VLCAD	yes	yes	C14:1	C14:1
6	IVA	yes	yes	C5	C5
7	MCC	yes	yes	C5OH/C4DC	C5OH/C4DC
8	BTK	yes	yes	C0, C4, C5:1, C6, C8	C0, C4, C5:1,

9	MSUD	yes	yes	LEU	LEU
10	MCAD	yes	yes	C6, C8, C10:1	C0 low, C8, C10:1
11	PPA	yes	yes	C3, C16:1 OH	C3, C16:1 OH
12	PKU	yes	yes	PHE	PHE
13	CIT	yes	yes	CIT	CIT
14	PKU	yes	yes	PHE	PHE
15	MCAD	yes	yes	C6, C6DC, C8, C10, C10:1, C12:1	C6, C6DC, C8, C10, C10:1
16	GAI	yes	yes	C5DC	C5DC
17	PKU	yes	yes	PHE	PHE

Finally, the established performance characteristics and method comparison at the analytical and clinical levels show that using the Neo Base Non-derivatized MSMS kit on the PerkinElmer TQD platform provides performance that is equivalent to the performance of the kit when used on the predicate platforms.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

PerkinElmer
c/o Kay Taylor
Director, Regulatory and Clinical Affairs
8275 Carloway Road
Indiannapolis, IN 46236

AUG 23 2010

Re: k093916
Trade Name: NeoBase Non-derivatized MSMS reagent kit
Regulation Number: 21 CFR 862.1055
Regulation Name: Newborn screening test system for amino acids, free carnitine, and acylcarnitines using tandem mass spectrometry
Regulatory Class: Class II
Product Codes: NQL
Dated: August 10, 2010
Received: August 11, 2010

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.
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): **K093916**

Device Name: **NeoBase Non-derivatized MSMS Kit**

Indications for Use:

The Neobase Non-derivatized MSMS reagent kit (for use on the PerkinElmer TQD MSMS Screening System) is intended for the measurement and evaluation of amino acids, succinylacetone, free carnitine, and acylcarnitine concentrations from newborn heel prick blood samples dried on filter paper.

Quantitative analysis of these analytes (Table 1) and their relationship with each other is intended to provide analyte concentration profiles that may aid in screening newborns for metabolic disorders.

Table 1. Analytes measured by the NeoBase™ Non-derivatized MSMS Kit.

ANALYTE NAME	ABBREVIATION
Amino acids	
Alanine	Ala
Arginine	Arg
Citrulline	Cit
Glycine	Gly
Leucine/Isoleucine/Hydroxyproline*	Leu/Ile/Pro-OH
Methionine	Met
Ornithine	Orn
Phenylalanine	Phe
Proline	Pro
Tyrosine	Tyr
Valine	Val

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ANALYTE NAME (continued)	ABBREVIATION
Carnitines	
Free carnitine	C0
Acetylcarnitine	C2
Propionylcarnitine	C3
Malonylcarnitine / 3-Hydroxy-butyrylcarnitine*	C3DC/C4OH
Butyrylcarnitine	C4
Methylmalonyl / 3-Hydroxy-isovalerylcarnitine*	C4DC/C5OH
Isovalerylcarnitine	C5
Tiglylcarnitine	C5:1
Glutarylcarnitine / 3-Hydroxy-hexanoylcarnitine*	C5DC/C6OH
Hexanoylcarnitine	C6
Adipylcarnitine	C6DC
Octanoylcarnitine	C8
Octenoylcarnitine	C8:1
Decanoylcarnitine	C10
Decenoylcarnitine	C10:1
Decadienoylcarnitine	C10:2
Dodecanoylcarnitine	C12
Dodecenoylcarnitine	C12:1
Tetradecanoylcarnitine (Myristoylcarnitine)	C14
Tetradecenoylcarnitine	C14:1
Tetradecadienoylcarnitine	C14:2
3-Hydroxy-tetradecanoylcarnitine	C14OH
Hexadecanoylcarnitine (Palmitoylcarnitine)	C16
Hexadecenoylcarnitine	C16:1
3-Hydroxy-hexadecanoylcarnitine	C16OH
3-Hydroxy-hexadecenoylcarnitine	C16:1OH

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ANALYTE NAME (continued)	ABBREVIATION
Octadecanoylcarnitine (Stearoylcarnitine)	C18
Octadecenoylcarnitine (Oleylcarnitine)	C18:1
Octadecadienoylcarnitine (Linoleylcarnitine)	C18:2
3-Hydroxy-octadecanoylcarnitine	C18OH
3-Hydroxy-octadecenoylcarnitine	C18:1OH
Ketones	
Succinylacetone	SA

* Analytes in these rows are either isomers or isobars and cannot be distinguished in the tandem mass spectrometry experiment.

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)

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