May 3, 2019

PerkinElmer Inc.
Brian Ciccariello
Sr. Manager Regulatory Affairs
940 Winter Street
Waltham, MA 02451

Re: K190266
Trade/Device Name: NeoLSD MSMS Kit
Regulation Number: 21 CFR 862.1488
Regulation Name: Lysosomal storage disorder newborn screening test system
Regulatory Class: Class II
Product Code: PQW, PQT, PQU, PQV, QCL, QCM
Dated: February 6, 2019
Received: February 8, 2019

Dear Brian Ciccariello:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. 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 Part

801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190266

Device Name
NeoLSD MSMS Kit

Indications for Use *(Describe)*
The NeoLSD™ MSMS kit is intended for the quantitative measurement of the activity of the enzymes acid-β-glucocerebrosidase (ABG), acid-sphingomyelinase (ASM), acid α glucosidase (GAA), β galactocerebrosidase (GALC), α-galactosidase A (GLA) and α-L-iduronidase (IDUA) in dried blood spots (DBS) from newborn babies. The analysis of the enzymatic activity is intended as an aid in screening newborns for the following lysosomal storage disorders (LSD) respectively; Gaucher Disease, Niemann-Pick A/B Disease, Pompe Disease, Krabbe Disease, Fabry Disease, and Mucopolyaccharidosis Type I (MPS I) Disease.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

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

The assigned number is K190266

Date: February 06, 2019

Submitted by: PerkinElmer Inc
940 Winter Street
Waltham MA 02451

Contact Person: Brian Ciccariello
Tel: 781-663-5651

Trade Name: NeoLSD MSMS Kit

Common Name: NeoLSD MSMS Kit

Regulation: 21 CFR 862.1488

Classification Name: Lysosomal storage disorder newborn screening test system

Classification: 75 Chemistry

Product Code: PQW, PQT, PQU, PQV, QCL, QCM

Predicate device: NeoLSD MSMS Kit (K173829)

Intended Use:

The NeoLSD MSMS Kit is intended for the quantitative measurement of the activity of the enzymes acid-β- glucocerebrosidase (ABG), acid-sphingomyelinase (ASM), acid-α-glucosidase (GAA), β-galactocerebrosidase (GALC), α- galactosidase A (GLA) and α-L- iduronidase (IDUA) in dried blood spots (DBS) from newborn babies. The analysis of the enzymatic activity is intended as an aid in screening newborns for the following lysosomal storage disorders (LSD) respectively; Gaucher Disease, Niemann-Pick A/B Disease, Pompe Disease, Krabbe Disease, Fabry Disease, and Mucopolysaccharidosis Type I (MPS I) Disease.

Device Description:

The NeoLSD MSMS test system uses mass spectrometry to quantitatively measure the activity of six lysosomal enzymes simultaneously from a dried blood spot sample. The NeoLSD MSMS test system is comprised of:

1. NeoLSD MSMS kit, including substrates, internal standards, solutions and controls

The NeoLSD MSMS Kit will contain sufficient reagents and consumables to perform 960 assays (10 x 96-well plates) as listed in the following table.

Component	**Description**
Kit insert	Instructions for use
QC certificate	QC certificate showing the kit lot specific Kit Control results determined by the manufacturer, and the 1 SD limits.
Internal Standards Substrate Mix	1 vial or several vials of stable-isotope standards and designed substrates, the dried substrates and internal standards are a mixture of the 6 synthetic substrates, the corresponding 6 stable-isotope labeled internal standards, and sodium oleate
DBS controls	C1, C2, C3 control levels on DBS cassettes, manufactured from human blood with a hematocrit value of 45–50%.
Assay buffer	1 bottle of 40 mL buffer, ready-for-use succinate buffered (pH 4.7) salt solution
Extraction Solution	Ethyl acetate
Flow Solvent reconstitution solvent	The ready-for-use Flow Solvent contains acetonitrile, water, and formic acid.
Incubation/Sampling plate	20 x 96-well microplate, U-bottomed
Extraction plate	10 x 96-deep well microplate
Aluminum foil microplate covers	20 adhesive aluminum foil microplate covers
Microplate covers	10 x adhesive microplate covers
Plate barcode labels	30 plate barcodes

2. The QSight Instrument is comprised of:

   - QSight® 210 MD Mass Spectrometer
   - QSight HC Autosampler MD Instrument Software
   - QSight Binary Pump MD
   - Simplicity Instrument control software:
   - Simplicity Data Processing software (by sample):
   - PerkinElmer MSMS Workstation Data Processing Software

The NeoLSD MSMS kit evaluates enzyme activities by measuring the product generated when an enzyme reacts with a synthesized substrate to create a specific end product. The activities of the six lysosomal enzymes present in a 3.2 mm punch from a dried blood spot (DBS) are simultaneously measured by the NeoLSD MSMS kit. The punches are incubated with the assay reagent mixture which contains;

- six substrates, one corresponding to each lysosomal enzyme
- six stable-isotope mass-labeled internal standards (IS) each designed to chemically resemble each product generated
- a buffer to maintain the reaction pH, and to carry inhibitors to limit activity from competing enzymes if present and additives to enhance the targeted enzyme reactions.

Comparison Chart:

Comparison of the NeoLSD MSMS Kit with the predicate.

NeoLSD MSMS Kit		
Characteristics	**Proposed Device**	**Predicate (K173829)**
Intended Use/ Indications for Use	The NeoLSD MSMS Kit is intended for the quantitative measurement of the activity of the enzymes acid-β- glucocerebrosidase (ABG), acid-sphingomyelinase (ASM), acid-α-glucosidase (GAA), β-galactocerebrosidase (GALC), α- galactosidase A (GLA) and α-L-iduronidase (IDUA) in dried blood spots (DBS) from newborn babies. The analysis of the enzymatic activity is intended as an aid in screening newborns for the following lysosomal storage disorders (LSD) respectively; Gaucher Disease, Niemann-Pick A/B Disease, Pompe Disease, Krabbe Disease, Fabry Disease, and Mucopolysaccharidosis Type I Disease.	Same
Test Methodology	Quantitative mass spectrometric enzymatic activity assay	Same
Instrument / Software Platform	PerkinElmer QSight 210MD SMS Screening System: CTC PAL RSI Sample Manager, Spark Holland SPH1240 Binary Pump. Instrument Software: Simplicity, Data Processing software and with the PerkinElmer MSMS Workstation Software	Waters Acquity TQD instrument with MassLynx v4.1 firmware, with Waters 1525 sample pump, with Waters 2777c autosampler, with Waters NeoLynx v4.1 software and with the PerkinElmer MSMS Workstation Software
Sample Type	Punch from dried blood spot specimen	Same
Reportable Range (µmol/L/h)	**IDUA:** 0.19 – 22.3 **GAA:** 0.31 – 25.3 **ABG:** 0.79 – 20.0 **GLA:** 0.80 – 20.4 **ASM:** 0.16 – 13.8 **GALC**: 0.20 – 7.75	**IDUA:** 0.34 – 17.2 **GAA:** 0.44 – 24.2 **ABG:** 0.69 – 20.1 **GLA:** 0.97 – 20.9 **ASM:** 0.90 – 20.5 **GALC**: 0.63 – 6.3
Lower Limits of Measure (µmol/L/h)	**IDUA**: LoB=0.044, LoD=0.13, LoQ=0.19 **GAA**: LoB=0.080, LoD=0.31, LoQ=0.31 **ABG**: LoB=0.114, LoD=0.79, LoQ=0.79 **GLA**: LoB=0.519, LoD=0.80, LoQ=0.80 **ASM**: LoB=0.046, LoD=0.16, LoQ=0.16 **GALC**: LoB=0.120, LoD=0.20, LoQ=0.20	**IDUA**: LoB=0.059, LoD=0.24, LoQ=0.34 **GAA**: LoB=0.073, LoD=0.39, LoQ=0.44 **ABG**: LoB=0.165, LoD=0.63, LoQ=0.69 **GLA**: LoB=0.476, LoD=0.97, LoQ=0.97 **ASM**: LoB=0.110, LoD=0.27, LoQ=0.90 **GALC**: LoB=0.106, LoD=0.34, LoQ=0.63

Calibrators / Standards	Molecular Weights & Concentrations of Internal Standards: **IDUA:** 430.26 / 15.0 µM **GAA:** 502.32 / 24.0 µM **ABG:** 390.38 / 20.0 µM **GLA:** 488.31 / 24.0 µM **ASM:** 404.40 / 15.0 µM **GALC:** 416.40 / 10.0 µM	Same
Controls	3 levels of control material, human blood based	Same

Expected Values (µmol/L/h)

	N	0.1%	0.2%	0.3%	2.5%	97.5%
IDUA	2488	1.36	1.51	1.86	3.31	12.55
GAA	2488	2.32	2.54	2.79	4.23	19.55
ABG	2488	1.40	1.78	1.96	3.66	18.95
GLA	2488	3.83	4.74	5.44	7.59	41.99
ASM	2488	1.32	1.43	1.57	2.32	8.01
GALC	2488	0.80	1.01	1.07	1.62	14.90

	N	0.1%	0.2%	0.3%	2.5%	97.5%
IDUA	5041	2.06	2.55	2.62	3.82	13.2
GAA	5041	2.33	2.69	2.92	4.28	17.5
ABG	5041	2.85	3.16	3.33	4.74	20.1
GLA	5041	3.04	3.37	3.62	4.81	25.8
ASM	5041	2.12	2.21	2.37	3.15	12.9
GALC	5041	0.43	0.52	0.56	0.95	9.34

Precision

	Sample Activity Range	Sample CV% Range
IDUA	0.76-16.4	8.9%-15.8%
GAA	0.95-24.7	7.3%-12.8%
ABG	1.05-14.7	13.9%-22.8%
GLA	1.03-17.6	7.3%-16.1%
ASM	0.56-12.2	8.1%-14.5%
GALC	0.27-7.75	6.4%-13.4%

	Sample Activity Range	Sample CV% Range
IDUA	0.92-15.7	8.7%-18.7%
GAA	1.29 – 22.4	6.9%-16.7%
ABG	1.15-19.3	12.5%-23.2%
GLA	1.23-19.3	9.1%-16.1%
ASM	0.92-21.5	10.4%-16.7%
GALC	0.45-5.58	11.4%-22.7%

Summary of Studies:

Precision:

The NeoLSD kit precision was determined based on the recommendations of the CLSI guideline EP5-A2 and presented in the tables below. The variation of the NeoLSD MSMS kit is based on 108 determinations: 54 plates measured over 22 working days, each plate having 2 replicates per sample. The samples were measured on 3 QSight systems using 3 kit lots.

NeoLSD QSight 22-day precision results.

ABG	n	Mean	Repeatability		Within-lab		Between-lot		Total variation	
		µmol/L/h	SD	CV%	SD	CV%	SD	CV%	SD	CV%
1	108	1.05	0.11	10.7	0.24	22.7	0.02	2.4	0.24	22.8
2	108	2.33	0.30	13.0	0.38	16.5	0.11	4.8	0.40	17.2
3	108	6.56	0.71	10.8	0.93	14.1	0.19	2.8	0.95	14.4
4	108	13.0	1.21	9.30	1.73	13.3	0.50	3.9	1.80	13.9
5	108	14.7	2.35	15.9	2.97	20.2	0.29	2.0	2.99	20.3

ASM	n	Mean	Repeatability		Within-lab		Between-lot		Total variation	
		µmol/L/h	SD	CV%	SD	CV%	SD	CV%	SD	CV%
1	108	0.56	0.06	10.0	0.08	14.0	0.02	3.9	0.08	14.5
2	108	1.12	0.09	8.1	0.11	9.6	0.05	4.1	0.12	10.4
3	108	3.47	0.24	6.9	0.27	7.7	0.09	2.5	0.28	8.1
4	108	7.40	0.71	9.6	0.83	11.2	0.25	3.3	0.86	11.7
5	108	12.2	1.13	9.3	1.32	10.9	0.40	3.3	1.38	11.4

GALC	n	Mean	Repeatability		Within-lab		Between-lot		Total variation	
		µmol/L/h	SD	CV%	SD	CV%	SD	CV%	SD	CV%
1	108	0.27	0.03	10.1	0.04	13.2	0.01	2.1	0.04	13.4
2	108	0.56	0.05	8.3	0.07	12.6	0.02	3.6	0.07	13.1
3	108	2.58	0.18	7.1	0.19	7.3	0.02	0.8	0.19	7.4
4	108	4.74	0.24	5.1	0.30	6.4	0.03	0.6	0.30	6.4
5	108	7.75	0.78	10.0	0.82	10.5	0.34	4.4	0.89	11.4

IDUA	n	Mean	Repeatability		Within-lab		Between-lot		Total variation	
		µmol/L/h	SD	CV%	SD	CV%	SD	CV%	SD	CV%
1	108	0.76	0.11	15.1	0.12	15.6	0.02	2.3	0.12	15.8
2	108	1.33	0.12	9.1	0.18	13.5	0.03	2.4	0.18	13.7
3	108	2.71	0.20	7.2	0.25	9.2	0.09	3.3	0.26	9.7
4	108	7.75	0.55	7.0	0.69	8.9	0.04	0.5	0.69	8.9
5	108	16.4	1.78	10.8	2.01	12.2	0.34	2.1	2.04	12.4

GLA	n	Mean µmol/L/h	Repeatability		Within-lab		Between-lot		Total variation	
			SD	CV%	SD	CV%	SD	CV%	SD	CV%
1	108	1.03	0.11	10.7	0.16	15.9	0.03	2.6	0.17	16.1
2	108	2.46	0.19	7.5	0.26	10.4	0.04	1.7	0.26	10.5
3	108	6.44	0.49	7.6	0.64	9.9	0.01	0.2	0.64	9.9
4	108	12.2	0.58	4.8	0.95	7.8	0.20	1.6	0.97	7.9
5	108	17.6	1.15	6.5	1.27	7.2	0.15	0.8	1.28	7.3

GAA	n	Mean µmol/L/h	Repeatability		Within-lab		Between-lot		Total variation	
			SD	CV%	SD	CV%	SD	CV%	SD	CV%
1	108	0.95	0.08	8.4	0.12	12.7	0.02	1.7	0.12	12.8
2	108	2.80	0.22	7.8	0.24	8.5	0.05	1.7	0.24	8.7
3	108	8.01	0.55	6.9	0.58	7.2	0.11	1.4	0.59	7.3
4	108	17.1	1.76	10.3	1.95	11.4	0.29	1.7	1.97	11.5
5	108	24.7	1.54	6.2	1.81	7.3	0.23	0.9	1.82	7.4

Limit of Blank, Detection and Quantification:

The limits of blank and detection were determined according to the CLSI guideline EP17-A2 and presented in the table below. The limit of blank (LoB) for the NeoLSD MSMS kit is defined as the 95th percentile of a distribution of blank samples determine with 73 determinations. The limit of detection (LoD) of the kit is based on 75 determinations done with low level samples for the QSight 210 MD Screening System.

NeoLSD limit of blank (LoB) and limit of detection (LoD) with QSight.

Enzyme	LoB	LoD
ABG	0.114	0.79
ASM	0.046	0.16
GALC	0.120	0.20
IDUA	0.044	0.13
GLA	0.519	0.80
GAA	0.080	0.31

The Limit of Quantitation (LoQ) is defined as the lowest activity fulfilling the total CV% requirement of the assay. For ABG, GLA and IDUA the CV% requirement is <40%. For ASM and GAA <30% and for GALC <50%. If the imprecision criterion was met for activities below LoD, the LoQ was set to be equal to the LoD. The table shows the LoQ results and imprecision observed at these activities:

NeoLSD Limit of Quantitation

Enzyme	QSight
	LoQ (µmol/L/h)
ABG	0.79
ASM	0.16
GALC	0.20
IDUA	0.19
GLA	0.80
GAA	0.31

Linearity:

Linearity was determined in accordance with CLSI guideline EP06-A. The data fulfills the acceptance criteria of the study for the PerkinElmer QSight 210 MD Screening System. The linear range for NeoLSD MSMS kit using the QSight is summarized in below.

NeoLSD linear range

Enzyme	QSight	
	Linear Range Lower Limit (µmol/L/h)	Linear Range Upper Limit (µmol/L/h)
ABG	0.39	20.0
ASM	0.09	13.8
GALC	0.18	7.75
IDUA	0.08	22.3
GLA	0.60	20.4
GAA	0.11	25.3

Interference:

Refer to the kit insert for interference information.

Screening Performance:

The screening performance of the NeoLSD MSMS kit on QSight and Waters Acquity TQD was compared in a clinical study at US newborn screening laboratory (Site A). In the study 2489 routine newborn samples were tested. Samples tested were from newborns ≤ 48 hours old. The study population was enriched with 12 archived confirmed LSD positive newborn DBS specimens.

The initial cut-off values were based on a percentage of population median activity. The retest cut-off values were set 5% lower from the initial cut-off percentage. The cut-off percentages were applied to daily medians established based on the initial routine sample results for the day. The initial and retest cut-off percentages used in the study are shown below. The final results for the screening performance including confirmed positive specimens are presented below. Two retrospective confirmed positive Krabbe specimens and one routine specimen were categorized as "invalid result". In routine newborn screening, if a specimen result is categorized as invalid result, a new dried bloodspot specimen should be obtained, and retesting performed using age-specific cut-off values. Invalid results are excluded from the tabulations.

Descriptive statistics for the US Site A.

QSight									
Enzyme	n	Enzyme activity (µmol/L/h)						Initial cut-off	Retest cut-off
		Range*	Mean	Median	Lower percentiles				
					0.1%	0.2%	0.3%		
ABG	2489	1.06 – 102	9.47	8.83	1.40	1.78	1.96	25%	20%
ASM	2489	1.09 – 23.7	4.55	4.30	1.32	1.43	1.57	35%	30%
GALC	2489	0.48 – 50.0	5.57	4.70	0.80	1.01	1.07	25%	20%
IDUA	2489	0.34 – 21.0	7.30	7.05	1.36	1.51	1.86	25%	20%
GLA	2489	2.21 – 133	17.5	15.3	3.83	4.74	5.44	35%	30%
GAA	2489	1.87 – 31.8	10.1	9.53	2.32	2.54	2.79	25%	20%

TQD									
Enzyme	n	Enzyme activity (µmol/L/h)						Initial cut-off	Retest cut-off
		Range*	Mean	Median	Lower percentiles				
					0.1%	0.2%	0.3%		
ABG	2489	1.09 – 104	9.17	8.50	1.36	1.70	1.88	25%	20%
ASM	2489	1.11 – 24.2	4.63	4.39	1.36	1.43	1.60	35%	30%
GALC	2489	0.43 – 47.0	5.08	4.25	0.68	0.85	0.92	25%	20%
IDUA	2489	0.32 – 21.3	7.24	6.99	1.34	1.44	1.83	25%	20%
GLA	2489	1.84 – 144	16.9	14.6	3.64	4.27	4.79	35%	30%
GAA	2489	1.92 – 35.6	10.9	10.2	2.40	2.65	2.88	25%	20%

* Some results were outside the measuring range and cannot be considered accurate (see section "REPORTING RESULTS").

Screening performance using percentage of daily median cut-off (Invalid results and samples with no repeat result excluded).

Gaucher (ABG)		TQD		
		Screening Positive	Screening Negative	Total
QSight	Screening Positive	3*	0	3
	Screening Negative	0	2487	2487
	Total	3	2487	2490

*Includes 2 retrospective confirmed positive samples

Niemann-Pick A/B (ASM)		TQD		
		Screening Positive	Screening Negative	Total
QSight	Screening Positive	2*	0	2
	Screening Negative	0	2488	2488
	Total	2	2488	2490

*Includes 1 retrospective confirmed positive sample

Krabbe (GALC)		TQD		
		Screening Positive	Screening Negative	Total
QSight	Screening Positive	4*	0	4
	Screening Negative	0	2486	2486
	Total	4	2486	2490

*Includes 1 retrospective confirmed positive sample

MPS I (IDUA)		TQD		
		Screening Positive	Screening Negative	Total
QSight	Screening Positive	6*	0	6
	Screening Negative	0	2484	2484
	Total	6	2484	2490

*Includes 1 retrospective confirmed positive sample

Fabry (GLA)		TQD		
		Screening Positive	Screening Negative	Total
QSight	Screening Positive	6*	0	6
	Screening Negative	0	2484**	2484
	Total	6	2484	2490

* Includes 2 retrospective confirmed positive samples
**Includes 2 retrospective confirmed positive female samples

Pompe (GAA)		TQD		
		Screening Positive	Screening Negative	Total
QSight	Screening Positive	1*	0	1
	Screening Negative	0	2489	2489
	Total	1	2489	2490

*Includes 1 retrospective confirmed positive sample

Conclusion:

The NeoLSD MSMS kit demonstrates analytical and screening performance that supports its substantial equivalency with the predicate device, NeoLSD MSMS kit (K173829).