January 23, 2019

The Binding Site Group, Ltd.
Natasha Verhaak
Regulatory Affairs Officer
8 Calthorpe Road
Birmingham, West Midlands, B15 1QT, UK

Re: K183151
Trade/Device Name: Optilite IgA CSF Kit
Regulation Number: 21 CFR 866.5510
Regulation Name: Immunoglobulins A, G, M, D, and E immunological test system
Regulatory Class: Class II
Product Code: CFN
Dated: November 6, 2018
Received: November 14, 2018

Dear Natasha Verhaak:

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,

Leonthena R. Carrington -S

Lea Carrington
Director
Division of Immunology
and Hematology 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)*
K183151

Device Name
Optilite IgA CSF Kit

Indications for Use *(Describe)*
The Optilite IgA CSF Kit is intended for the quantitative in vitro measurement of IgA in cerebrospinal fluid (CSF) using the Optilite analyser.

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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Optilite IgA CSF Kit
510(k) Submission Summary

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A. 510(k) Number:

K183151

B. Purpose for Submission:

New device

C. Measurand:

IgA

D. Type of Test:

Quantitative immunoturbidimetry

E. Applicant:

The Binding Site

F. Proprietary and Established Names:

Optilite® IgA CSF Kit

G. Regulatory Information:

1. Regulation section:
   21 CFR 866.5510, Immunoglobulins A, G, M, D, and E immunological test system

2. Classification:
   Class II

3. Product code:
   CFN – method, nephelometric, immunoglobulins (G, A, M)

4. Panel:
   Immunology (82)

H. Intended use:

1. Intended use(s):

The Optilite IgA CSF Kit is intended for the quantitative *in vitro* measurement of IgA in cerebrospinal fluid (CSF) using the Optilite analyser.

2. Indication(s) for use:

Same as Intended use.

3. Special conditions for use statement(s):

Prescription use only

4. Special instrument requirements:

The Binding Site Optilite turbidimetric analyser (K110035)

I. Device Description:

The Optilite IgA CSF Kit comprises the following reagents:

Latex Reagent: Supplied in stabilised liquid form. Preservatives: 0.025% sodium azide, 0.1% E-amino-n-caproic acid (EACA) and 0.01% benzamidine, 0.05% ProClin.

Calibrator and Controls: Pooled human serum, supplied in stabilised liquid form. Containing 0.099% sodium azide, 0.1% EACA and 0.01% benzamidine as preservatives. The concentration given on the quality control certificate has been obtained by comparison with the DA470k international reference material.

Reaction Buffer: Containing 0.099% sodium azide as a preservative.

J. Substantial equivalence information:

1. Predicate device name(s) and 510(k) number(s):
Beckman Coulter Low Concentration Immunoglobulin A (IGALC) reagent and Cerebrospinal Fluid Protein Calibrator (CSF CAL) (K993549)

2. Comparison with predicate:

Similarities		
Item	**Test device**	**Predicate**
Intended use	*In vitro* quantification of IgA in CSF.	*In vitro* quantification of IgA in CSF (also serum).
Analyte	IgA	Same
Traceability	DA470k	Same
Reagent type	Latex enhanced	Same
Reference interval	< 2.0mg/L	Same
Assay type	Quantitative	Same
Specimen type	CSF	CSF (also serum)
Differences		
Item	**Test device**	**Predicate**
Calibrator	Stabilised human serum	Human urine
Open vial stability	3 months	30 days
Antibody	Sheep anti-Human IgA antibody	Goat antihuman IgA
Method	Turbidimetric	Nephelometric
Measuring range	0.91 – 20 mg/L (1+0) 1.65 – 40 mg/L (1+1)	Initial: 2 – 70 mg/L Extended: 0.25 – 420 mg/L
Instrument	Binding Site Optilite	Beckman Coulter IMMAGE

K. Standards and Guidance documents referenced:

CLSI EP17-A2 Protocols for Determination of Limits of Detection and Limits of Quantitation; Approved Guideline
CLSI EP7-A2 Interference Testing in Clinical Chemistry, Approved Guideline - Second Edition
CLSI EP6-A: Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach
CLSI EP5-A2 Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline – Second Edition

L. Test Principle:

The determination of soluble antigen concentration by turbidimetric methods involves the reaction with specific antiserum to form insoluble complexes. When light is passed through the suspension formed a portion of the light is transmitted and focused onto a photodiode by an optical lens system. The amount of transmitted light is indirectly proportional to the specific protein concentration in the test sample. Concentrations are automatically calculated by reference to a calibration curve stored within the instrument.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

The precision study was based on CLSI EP5-A2 *Evaluation of Precision Performance of Clinical Quantitative Measurement Methods.* The study was performed over 5 working days, with 2 runs per day. Two users assessed 4 different samples, using 2 reagent lots each on 3 analysers.

Results:

Precision Summary									
	Mean (mg/L)	Within run		Between run		Between day		Total	
		SD	CV %	SD	CV %	SD	CV %	SD	CV %
Level 1	2.24	0.03	1.3	0.04	1.9	0.07	3.3	0.09	4.0
Level 2	3.53	0.09	2.5	0.08	2.3	0.16	4.4	0.20	5.6
Level 3	4.59	0.04	0.8	0.05	1.1	0.20	4.2	0.20	4.4
Level 4	28.90	0.48	1.7	0.56	1.9	0.40	1.4	0.84	2.9

b. Linearity/assay reportable range:

A linearity study was performed following CLSI Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline (EP6-A). The linearity of this assay has been confirmed using a serially diluted sample over the range of 1.0-44.8mg/L with deviation from linearity <10%.

c. Traceability, Stability, Expected values (controls, calibrators, or methods):

i) *Traceability*:

The calibration of the assay is traceable to ERM-DA470k/IFCC.

ii) Kit Stability:

Real-time stability – The Optilite IgA CSF Reagent, Calibrator and Controls have a shelf life of up to 18 months.
Open-vial stability - The Optilite IgA CSF Reagent, Calibrator and Controls can be stored, opened at 2-8°C for up to 3 months.
On-board stability – The Optilite IgA CSF Reagent can be stored on-board the Optilite Analyser for up to 30 days.

d. Detection limit:

The limit of quantitation (LoQ) for this assay is defined as the bottom of the measuring range, 0.91mg/L. The LoQ validation study was based on CLSI EP17-A2 Evaluation of the Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline – 2nd Edition.

e. Analytical specificity:

A study was performed following CLSI EP7-A2: Interference Testing in Clinical Chemistry, Approved Guideline. A CSF sample close to the medical decision point and an elevated CSF sample were tested. No significant assay interference effects were observed in CSF when tested with haemoglobin (2.5g/L), bilirubin (100mg/L), acetaminophen (1324µmol/L) or acetylsalicylic acid (3.63mmol/L).

f. Assay cut-off:

Not determined

2. Comparison studies:

a. Method comparison with predicate device:

A comparison study was performed by analysing 130 CSF samples (including 40 samples with analyte levels within the reference interval) using the Optilite IgA CSF Kit and an alternative commercially available assay. Passing Bablok regression analysis generated the following results:

Passing Bablok	Slope 95% CI	Intercept 95% CI
y= 1.05x –0.02	1.03 to 1.07	-0.07 to 0.05

Correlation coefficient
0.984

b. Matrix comparison:

None

3. Clinical studies:

a. Clinical Sensitivity:
None determined

b. Clinical specificity:
None determined

c. Other clinical supportive data (when a. and b. are not applicable):
Not applicable

4. Clinical cut-off**:**

None determined

5. Expected values/Reference range:

The reference range of <2.0 mg/L was transferred from literature in common with the predicate device.

N. Proposed Labelling:

The labelling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.