



May 28, 2019

The Binding Site Group Ltd.
Kanika Darbar
Regulatory Affairs Officer
The Binding Site Group Ltd.
8 Calthorpe Road
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Birmingham,
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B15 1QT,
UK

Re: K190686

Trade/Device Name: Optilite IgM 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: March 8, 2019
Received: March 18, 2019

Dear Kanika Darbar:

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,

Doug Jeffery, Ph.D.
Deputy Division Director
Division of Immunology and Hematology Devices
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K190686

Device Name

Optilite IgM CSF Kit

Indications for Use (Describe)

The Optilite IgM CSF Kit is intended for the quantitative in vitro measurement of IgM in cerebrospinal fluid (CSF) samples 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Optilite IgM CSF Kit 510(k) Submission Summary

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Preparation Date: 28-May-2019

A. 510(k) Number:

K190686

B. Purpose for Submission:

New device

C. Measurand:

IgM

D. Type of Test:

Quantitative immunoturbidimetry

E. Applicant:

The Binding Site

F. Proprietary and Established Names:

Optilite® IgM 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 IgM CSF Kit is intended for the quantitative *in vitro* measurement of IgM in cerebrospinal fluid (CSF) samples 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 IgM 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):

Human IgM CSF Kit for use on SPAPLUS K120750

2. Comparison with predicate:

Similarities		
Item	Test device	Predicate
Assay type	Quantitative	Same
Specimen Type	CSF	Same
Antibody	Sheep anti-human-IgM	Same
Intended use	Quantitative <i>in vitro</i> measurement of IgM in cerebrospinal fluid	Same
Calibration	Traceable to DA470k	Same
On-board stability	30 days	Same
Reference Interval	<1.3mg/L	same
Method	Turbidimetric	Same
Differences		
Item	Test device	Predicate
Measuring range	0.11 – 4.0mg/L (1+0 dilution) 1.0 - 40mg/L (1+9 dilution)	0.3 – 7.0mg/L (1+0 dilution) 3.0 – 70.0mg/L (1+9 dilution)
Calibrator	Liquid stabilised human serum	Lyophilised
Open Vial Stability	3 months	2 months
Instrument	Binding Site Optilite	Binding Site SPAPLUS

K. Standards and Guidance documents referenced:

CLSI EP17-A2 Evaluation of the Detection Capability for Clinical Laboratory Measurement Procedures; 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 studies were based on CLSI EP5-A2, where 4 sample preparations were tested in 2 runs per day (each of the 2 runs in duplicate) over 5 days using 3 analysers. Acceptance criteria were total precision (%CV<10%), within-run precision (%CV<5%), between-run precision (%CV<8%), and between-day precision (%CV<8%). A summary of the results is shown below. All results are in mg/L.

Results:

Precision Summary									
	Mean (mg/L)	Within run		Between run		Between day		Total	
		SD	CV %	SD	CV %	SD	CV %	SD	CV %
Level 1	0.20	0.01	3.9	0.00	1.5	0.01	5.9	0.01	7.2
Level 2	0.44	0.01	2.8	0.01	2.5	0.02	4.6	0.03	5.9
Level 3	1.20	0.03	2.2	0.03	2.6	0.02	1.3	0.04	3.6
Level 4	3.02	0.07	2.3	0.09	2.9	0.06	2.0	0.13	4.2

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 0.07 – 4.55 mg/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 IgM CSF Reagent, Calibrator and Controls have a shelf life of up to 19 months.

Open-vial stability - The Optilite IgM CSF Reagent, Calibrator and Controls can be stored, opened at 2-8°C for up to 3 months.

On-board stability – The Optilite IgM 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, 0.11mg/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:

Interferences were assessed according to CLSI EP7-A2 by testing samples at different IgM concentrations. Each sample was spiked with interfering substances and tested. For non-interference to be claimed, the mean results from the spiked samples must be within 10% of the mean of the control samples. The data demonstrated that the assay was not affected by the following substances at the concentrations given below.

Results:

Interferent	Concentration	Interferent	Concentration
Acetaminophen	1324µmol/L	Bilirubin	80mg/L
Acetylsalicylic Acid	3.62mmol/L	Haemoglobin	1g/L

f. Assay cut-off:

Not determined

2. Comparison studies:

a. Method comparison with predicate device:

A total of 239 samples were initially tested in this study, and these consisted of 219 native CSF samples and an additional 20 patient samples which were spiked with purified IgM.

155 of these tested samples were within the measuring range and were included in the regression analysis. These results are presented below.

N	Sample Range	Passing Bablok	Slope 95% CI	Intercept 95% CI
155	0.251–39.35 mg/L	$y = 1.02x + 0.07$	1.00 to 1.04	0.03 to 0.09

Pearson's r
0.997

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 <1.3 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.