



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

THE BINDING SITE GROUP LTD
STEPHANIE THOULESS
REGULATORY AFFAIRS
8 CALTHORPE RD
EDGBASTON
BIRMINGHAM B15 1QT
UK

December 18, 2015

Re: K152389

Trade/Device Name: Optilite® Hevylite® IgM Kappa Kit, Optilite® Hevylite® IgM
Lambda Kit

Regulation Number: 21 CFR § 866.5510

Regulation Name: Immunoglobulins A, G, M, D, and E immunological test system

Regulatory Class: II

Product Code: PDE, PDF

Dated: November 16, 2015

Received: November 18, 2015

Dear Ms. Thouless:

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. 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 Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the

electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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 Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Kelly Oliner -S

FOR
Leonthena Carrington, MBA, MS, MT(ASCP)
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: January 31, 2017
See PRA Statement below.

510(k) Number (if known)
K152389

Device Name
Optilite Hevylite IgM Kappa Kit
Optilite Hevylite IgM Lambda Kit

Indications for Use (Describe)

The Optilite Hevylite IgM Kappa Kit is intended for the quantitative in vitro measurement of IgM kappa (combined μ heavy and κ light chain) in serum using the Binding Site Optilite analyser. The test result is to be used with previously diagnosed Waldenström's macroglobulinaemia. The test result should be used in conjunction with other laboratory and clinical findings.

This assay has not been established for the diagnosis, monitoring and prognosis of Waldenström's macroglobulinaemia.

The Optilite Hevylite IgM Lambda Kit is intended for the quantitative in vitro measurement of IgM lambda (combined μ heavy and λ light chain) in serum using the Binding Site Optilite analyser. The test result is to be used with previously diagnosed Waldenström's macroglobulinaemia. The test result should be used in conjunction with other laboratory and clinical findings.

This assay has not been established for the diagnosis, monitoring and prognosis of Waldenström's macroglobulinaemia.

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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