



DEPARTMENT OF HEALTH & HUMAN SERVICES

AUG 11 2005

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Viramed Biotech AG
c/o Barry E. Menefee, Ph.D.
Chief of Operations
Viralab, Inc.
1730 South Ditmar Street
Oceanside, CA 92054

Re: k051169
Trade/Device Name: Borrelia B31 IgM Virablot®
Regulation Number: 21 CFR 866.3830
Regulation Name: Treponema Pallidum Treponemal Test Reagents
Regulatory Class: Class II
Product Code: LSR
Dated: June 28, 2005
Received: June 29, 2005

Dear Dr. Menefee:

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.

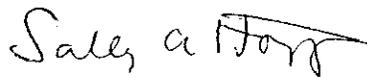
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

Page 2 –

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (240)276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>

Sincerely yours,



Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Appendix C. Indication of Use Statement

510(k) Number: K051169

Device Name: Borrelia B31 IgM Virablot®

Indication for Use:

The Viramed Biotech Borrelia B31 IgM ViraBlot® is an *in vitro* qualitative assay for the detection of IgM antibodies to *Borrelia burgdorferi* in human serum. It is intended for use in testing human serum samples which have been found positive or equivocal using an EIA or IFA test procedure for *B. burgdorferi* antibodies. Positive results from this Western Blot assay are supportive evidence of infection with *B. burgdorferi*, the causative agent of Lyme disease. The Viramed Biotech Borrelia B31 ViraBlot can be used during the acute phase (0-4 weeks of symptoms onset) of *B. burgdorferi* infection. After this early period, infected patients are usually found to be Western blot positive for IgG. A positive IgM test alone is not recommended for use in determining active disease in persons with illness of longer than one month.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X

AND/OR

Over-The-Counter Use

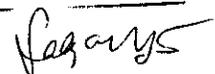
(Part 21 CFR 801 Subpart D)

(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off



Office of In Vitro Diagnostic
Evaluation and Safety