DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG 1 1 2005

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

Re: k051071
Trade/Device Name: Borrelia B31 IgG 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).

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: K051071

Device Name: Borrelia B31 IgG Virablot®

Indication for Use:
The Viramed Biotech Borrelia B31 IgG ViraBlot® is an *in vitro* qualitative assay for the detection of IgG antibodies to *Borrelia burgdorferi* in human serum. It is intended for use in the testing of 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 for Lyme disease. The Viramed Biotech Borrelia B31 IgG Virablot® can be used anytime after onset provided the EIA or IFA are positive or equivocal. It should also be used for follow-up when: 1) Only IgM antibodies were found positive in a Western blot, 2) IgG antibodies were found by Western blot but were not considered significant by the CDC criteria for a positive IgG Western blot, 3) previously tested seronegative individuals are shown to develop antibodies by an EIA or IFA test.

(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)

Division Sign-Off
Concurrence of CDRH, Office of Device Evaluation (ODE)
Office of In Vitro Diagnostic Devi...
Evaluation and Safety

Manufactured by Viramed Biotech AG, Behringstrasse, 11, Planegg/Steinkerchen, Germany D-82152
760 594-7285

510(k) K051071 | S1