

2/12/99

K981913

Attachment 3

510(k) SUMMARY

Submitted By:

Chembio Diagnostic Systems
3661 Horseblock Road
Medford, NY 11763

Contact Person:

Raymond Dattwyler, MD
phone: 516/444-2348 (office)
pager: 516/282-9611

Date Prepared:

May 26, 1998

Device Name:

Wampole PreVue™ *Borrelia burgdorferi* Antibody Detection Assay

Classification Name:

Reagent, *Borrelia* Serological Reagent [21 CFR §866.3830] 83 LSR

Predicate Device:

The Wampole *Borrelia burgdorferi* IgG/IgM ELISA
510(k) Document Control Number: K965131

Description of Device:

The Wampole PreVue™ *Borrelia burgdorferi* Antibody Detection Assay is a Class II *in vitro* medical diagnostic device that utilizes standard immunochromatographic-chromophore technology to qualitatively detect, in serum or whole blood, the presence of IgG and IgM antibodies to recombinant *Borrelia burgdorferi* antigens, as an aid in the diagnosis of Lyme Disease. It consists of a plastic housing, containing an absorbent material that collects the specimen and, with the addition of buffer, delivers it and adjacent adsorbed reagents, onto a chromatographic strip, onto which recombinant test antigen and control antibodies have been adsorbed within their respective test and control detection zones. As the mixture migrates along the strip, gold-conjugated antibodies specific for human IgG and IgM bind to the antibodies in the specimen. Antibodies specific for *Borrelia burgdorferi* antigens, if present, will bind to the adsorbed recombinant antigens in the test zone, resulting in a visually detectable colored line due to the presence of gold-conjugated antibodies, which are bound to the specimen antibodies. If no antibodies to *Borrelia burgdorferi* are present, no line will appear in the test zone. A line will always appear in the control zone, indicating a valid result, as goat anti-human IgG antibodies adsorbed in the control zone bind excess IgG in the specimen, which have been bound to the gold-conjugate.

The Wampole *PreVue*[™] *Borrelia burgdorferi* Antibody Detection Assay is a first step presumptive test for Lyme Disease antibodies, and is substantially equivalent to the Wampole *Borrelia burgdorferi* IgG/IgM ELISA.

Intended Use of the Device:

The Wampole *PreVue*[™] *Borrelia burgdorferi* Antibody Detection Assay is a single use, unitized immunochromatographic test that uses recombinant *B. burgdorferi* antigens for the qualitative presumptive (first step) detection of IgG and IgM antibodies to *B. burgdorferi* in human serum or whole blood. This test should be used only in patients with history, signs and symptoms that are consistent with Lyme disease. The TBD Lyme test is intended for use in clinical and physicians' office laboratories.

Technological Characteristics:

The Wampole *PreVue*[™] *Borrelia burgdorferi* Antibody Detection Assay is similar in technology to numerous immunochromatographic serology test devices. Examples include devices that detect IgG against *H. pylori*, or heterophile antibodies present with Infectious Mononucleosis. However, the test antigens utilized in the Wampole *PreVue*[™] *Borrelia burgdorferi* Antibody Detection Assay are derived from surface proteins of *Borrelia burgdorferi*. A unique difference is that the antigens used in the Wampole *PreVue*[™] *Borrelia burgdorferi* Antibody Detection Assay are recombinant, while other Lyme Disease serological tests use antigens purified from cultured *B. burgdorferi*. The use of recombinant antigens allows for improved specificity, as the epitopes that are cross-reactive with other, non-specific antibodies, have been deleted. Recombinant technology also allows for a continued supply of high-quality, uniform antigen, which is not dependent upon the repeated passage of any particular strain of *B. burgdorferi*.



FEB 12 1999

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Chembio Diagnostic Systems, Inc.
c/o Raymond Dattwyler, M.D.
Brook Biotechnologies
25 East Loop Road
Stonybrook, NY 11790

Re: K981913
Trade Name: PreVue™ *Borrelia burgdorferi* Antibody Detection Assay
Regulatory Class: II
Product Code: LSR
Dated: December 3, 1998
Received: December 4, 1998

Dear Dr. Dattwyler:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

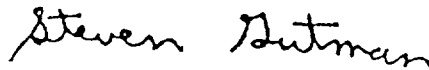
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770)488-7655.

This letter will allow you to begin marketing your device as described in your 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 advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll free number (800) 638-2041 or at (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>"

Sincerely yours,



Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Attachment 2

INDICATIONS FOR USE STATEMENT

510(k) Number: K981913

Device Name: Wampole PreVue™ *Borrelia burgdorferi* Antibody Detection Assay

Indications for Use: The Wampole PreVue™ *Borrelia burgdorferi* Antibody Detection Assay is a single use, unitized immunochromatographic test that uses recombinant *B. burgdorferi* antigens for the qualitative presumptive (first step) detection of IgG and IgM antibodies to *B. burgdorferi* in human serum or whole blood. This test should be used only in patients with history, signs and symptoms that are consistent with Lyme disease. The Wampole PreVue™ *Borrelia burgdorferi* Antibody Detection Assay is intended for use in clinical and physicians' office laboratories.

PRESCRIPTION USE X

Woody Dubois

(Division Sign Off)

Division of Clinical Laboratory Devices

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