

510(k) SUMMARY

January 28, 1998

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: _____.

Applicant Device

BBI-Biotech Research Laboratories *B. burgdorferi* IgM Western blot kit
Boston Biomedica, Inc.
375 West Street
West Bridgewater, MA 02379

Predicate Device

B. burgdorferi (IgM) Marblot Strip Test System
510(k) K951709
MarDx Diagnostics, Inc.
5919 Farnsworth Ct.
Carlsbad, CA 92008

Device Description

The device is a collection of cGMP manufactured critical components needed to perform a Western blot test that will detect *B. burgdorferi* IgM antibody in naturally infected humans. It includes nitrocellulose strips upon which sodium dodecyl sulfate solubilized and polyacrylamide separated *B. burgdorferi* proteins have been transferred, an IgM Positive Control, a Negative Control, an anti-IgM alkaline phosphatase conjugate concentrate, a buffer concentrate, diluent powder, an NBT/BCIP substrate, Blot Reading Guide, Package Insert, and Results Record Forms.

Intended Use

The BBI-Biotech *B. burgdorferi* IgM Western blot kit is intended to provide supportive evidence of infection with *B. burgdorferi* by determining the specific protein reactivities of human serum specimens previously found to be reactive on enzyme immunoassay or indirect immunofluorescence screening assays. The kits will be made available to clinical laboratory professionals in public health laboratories and clinical laboratories.

Technological Comparison with the Predicate Device

Both devices use the same type of technology. They differ primarily in the strains of *B. burgdorferi* used, the type of initial antigen preparation, the requirement for a pre-wetting step, the length of incubation times, the standardization of substrate incubation, the method used to identify bands of interest, and the positive interpretation criterion.

Performance comparisons

The two devices were substantially equivalent when tested with first physician visit, verified infected patient samples and with randomly selected enzyme immunoassay positive patient samples. The Applicant Device claims higher specificity than the Predicate Device with blood samples from random blood donors and from patients with syphilis antibody, rheumatoid arthritis, and systemic lupus erythematosus.

Prepared by

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MAR = 5 1999

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Debra A. Petit
Manager, Clinical Trials and Regulatory Affairs
Boston Biomedica, Inc.
375 West Street
W. Bridgewater, MA 02379

Re: K980351
Trade Name: BBI-Biotech *B. burgdorferi* IgM Western Blot Kit
Regulatory Class: II
Product Code: LSR
Dated: December 17, 1998
Received: December 21, 1998

Dear Ms. Petit:

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.

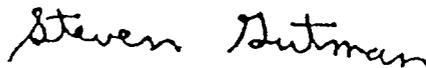
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770)488-7655.

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

510(k) Number (if known): K980351

Device Name: BBI-Biotech Research Laboratories *B. burgdorferi* IgM Western blot kit

Indications For Use:

The BBI-Biotech *B. burgdorferi* IgM Western blot kit is intended to provide supportive evidence of infection with *B. burgdorferi* by determining the specific protein reactivities of human serum specimens previously found to be reactive on enzyme immunoassay or indirect immunofluorescence screening assays. The kits will be made available to clinical laboratory professionals in public health laboratories and clinical laboratories.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Woody Dubois
(Division Sign Off)
Division of Clinical Laboratory Devices
510(k) Number K980351

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)