K951709

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Attachment A - 510K Summary

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

Identification of reference device:

I. MarDx Lyme Disease IgM EIA Test System (K894293).
II. The Lyme Western blot procedure developed and utilized by Dr. Allen Steere, MD, Tufts Medical Center, Boston , MA (Dressler et al, Journal of Infectious Diseases, 1993; 167:392-400).
III. The physicians diagnosis of the Academic Reference Centers (ARCS) panel maintained by the CDC, Fort Collins, CO.

Description of the new device:
The MarDx Lyme Disease (IgM) Marblot Strip Test System is a Western blot device for the detection of human IgM antibodies directed to the organism *Borrelia burgdorferi.* The device is similar in function to other solid phase enzyme immunoassays (EIA), but differs in its ability to discriminate the individual antibody specificities directed against the organism.

Statement of the intended use:
MarDx Lyme Disease (IgM) Marblot Strip Test System is a Western blot assay for the qualitative detection of human IgM antibody to *B. burgdorferi.* The MarDx Lyme Disease (IgM) Marblot Strip Test System is intended for use in testing human serum samples which have been found positive or equivocal using an EIA or IFA test procedure.

Comparison / Technology characteristics of the device:
The Western blot is very similar to the EIA in that both are enzyme immunoassays. In both assays the enzyme labeled bound patient antibodies are detected with a chromogenic substrate that is converted to a visible colored product at the reaction site. The final end product of the Western blot and the EIA do differ somewhat. The EIA end product is not stable over time and must be read by spectrophotometric methods within a few minutes. In contrast Western blot strips are stable for many years and may be read at any time. This difference does not effect the safety or effectiveness of the device.

Description and conclusions of the clinical studies:
Thirteen hundred and forty one sera were tested by reference Western blot and EIA methodologies to determine the agreement, sensitivity, and specificity of the MarDx Lyme Disease (IgM) Marblot Strip Test System. The data indicates that the MarDx Marblot Lyme IgM Test has a high sensitivity and specificity relative to the Steere Western blot and the MarDx Lyme Disease IgM EIA Test System reference procedure, thus performs at least as well as the predicate devices.

Sincerely,

Arthur Markovits, M.S.P.H.
President
MarDx Diagnostics, Inc.

Date: 4/11/95

Barry E. Menefee, Ph.D.
Vice President Scientific Affairs
MarDx Diagnostics, Inc.

Date: 4/11/95