DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
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See PRA Statement below.

510(k) Number *(if known)*

K173496

Device Name

Sofia 2 Lyme FIA
Sofia Lyme Control Set

Indications for Use *(Describe)*

Sofia 2 Lyme FIA:
The Sofia 2 Lyme FIA employs immunofluorescence for the rapid differential detection of human IgM and IgG antibodies to *Borrelia burgdorferi* from finger-stick whole blood specimens from patients suspected of *B. burgdorferi* infection of at least 2 weeks' duration. The Sofia 2 Lyme FIA is intended for use as an aid in diagnosis of Lyme disease. A negative result does not preclude infection with *B. burgdorferi*. Positive results must be confirmed by testing with a corresponding second-tier *B. burgdorferi* Western blot assay. Test results are to be used in conjunction with information obtained from the patient's clinical evaluation and other diagnostic procedures. The assay is to be performed on the Sofia 2 instrument. Professional guidelines should be consulted regarding testing and treatment for Lyme disease when acute *B. burgdorferi* infection is suspected.

Sofia Lyme Control Set:
The Sofia Lyme Control Set is intended for use as assayed quality control materials to verify the performance of the Sofia Lyme FIA and Sofia 2 Lyme FIA test system.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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