October 9, 2024

Joe Shia, Director
LSI International Inc
504E Diamond Ave., Suite H
Gaithersburg, MD 20877 USA

Re: CR240359
CLIA Parent(s): k241869
Applicant: VivaChek Biotech (Hangzhou) Co., Ltd
Device: BioSieve Toxismart Reader; BioSieve Fentanyl FIA Home Test Kit; BioSieve Fentanyl FIA Pro Test Kit
Dated: June 27, 2024
Received: June 27, 2024
CLIA Effective Date: October 9, 2024

Categorization Notification (Waived)

Regulations codified at 42 CFR 493.15 et. seq., implementing the Clinical Laboratory Improvement Amendments of 1988, require the Secretary to provide for the categorization of specific clinical laboratory test systems by the level of complexity. Based upon these regulations, the following commercially marketed test system or assay for the analyte is categorized below:

Test System/Analyte(s): (SEE ATTACHMENT)

Waived status is applicable to test systems and their instructions approved by the FDA. We recommend that the test system instructions include a statement that the test system is waived under CLIA. Any modification to the test system including test system instructions or a change in the test system name must be submitted to the FDA for the evaluation of waiver. If you change the test system name or your company's name or if a distributor's name replaces your name, you must request another categorization by sending in the revised labeling along with a letter to FDA referencing the document number above.

This complexity categorization is effective as of the date of this notification and will be reported in FDA's CLIA Database: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/search.cfm . This categorization information may be provided to the user of the commercially marketed test system or assay as specified for the analyte indicated. FDA reserves the right to re-evaluate and re-categorize this test based upon additional information received.

If you have any questions regarding this complexity categorization, please contact Simona Puiu at simona.puiu@fda.hhs.gov.

Sincerely yours,

Courtney H. Lias, Ph.D.
Acting Office Director
OHT7: Office of In Vitro Diagnostics,
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Parent Number : k241869

Test System : Vivachek Biotech (hangzhou) Co., Ltd, BioSieve Toxismart Reader (BioSieve Fentanyl FIA Home Test Kit)
Analyte : Fentanyl
Complexity : WAIVED

Test System : Vivachek Biotech (hangzhou) Co., Ltd, BioSieve Toxismart Reader (BioSieve Fentanyl FIA Pro Test Kit)
Analyte : Fentanyl
Complexity : WAIVED