February 12, 2026

Healgen Scientific LLC
℅ Jenny Xia
Director
LSI International Inc
504 E Diamond Ave.
Suite H
Gaithersburg, Maryland 20877

Re: K252523
Trade/Device Name: Healgen® Accurate Oral Fluid Drug Test COT/THC; Healgen® Accurate Oral Fluid Drug Test
Regulation Number: 21 CFR 862.3870
Regulation Name: Cannabinoid Test System
Regulatory Class: Class II
Product Code: NFW, MKU
Dated: December 24, 2025
Received: December 29, 2025

Dear Jenny Xia:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and 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 (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the Quality Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See

the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

JOSEPH A. KOTAREK -S
Digitally signed by JOSEPH A. KOTAREK -S
Date: 2026.02.12 08:33:47 -05'00'

Joseph Kotarek
Branch Chief
Division of Chemistry and Toxicology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K252523

Device Name
Healgen® Accurate Oral Fluid Drug Test COT/THC
Healgen® Accurate Oral Fluid Drug Test

Indications for Use *(Describe)*
The Healgen® Accurate Oral Fluid Drug Test COT/THC is a lateral flow chromatographic immunoassay for the qualitative detection of cotinine (COT) and/or marijuana (THC) in oral fluid at the following cut-off concentrations:

Test	Calibrator	Cut-off (ng/mL)
Cotinine (COT)	(-) Cotinine	30
Marijuana (THC)	Delta-9-Tetrahydrocannabinol	40

This test provides only a preliminary result. An alternative laboratory test must be used to confirm the results provided by this drug test. Liquid chromatography mass spectrometry (LC/MS) is the preferred method for the confirmation test.

The Healgen® Accurate Oral Fluid Drug Test is a competitive binding lateral flow immunochromatographic assay for the qualitative and simultaneous detection of Marijuana (THC) and Cotinine in human oral fluid at the cutoff concentrations listed below and their metabolites:

Test	Calibrator	Cut-off (ng/mL)
Cotinine (COT)	(-) Cotinine	30
Marijuana (THC)	Delta-9-Tetrahydrocannabinol	40

This assay provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography mass spectrometry (GC/MS) and liquid chromatography mass spectrometry (LC/MS) are the preferred confirmatory methods.

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.

510(k) SUMMARY
K252523

1. Date: December 24, 2025

2. Submitter:
HEALGEN SCIENTIFIC LLC
5213 Maple Street
Bellaire, TX 77401

3. Contact person:
Jenny Xia
LSI International Inc.
504 East Diamond Ave., Suite H
Gaithersburg, MD 20877
Telephone: 301-525-6856
Email:jxia@lsi-consulting.org

4. Device Names: Healgen® Accurate Oral Fluid Drug Test COT/THC
Healgen® Accurate Oral Fluid Drug Test

Classification:

Product Code	CFR #	Panel
NFW	21 CFR, 862.3870 Cannabinoids Test System	Toxicology
MKU	21 CFR, 862.3220 Cotinine Test System	Toxicology

5. Predicate Devices:

Healgen® Accurate Oral Fluid Drug Test, K223162

6. Intended Use

The Healgen® Accurate Oral Fluid Drug Test COT/THC is a lateral flow chromatographic immunoassay for the qualitative detection of cotinine (COT) and/or marijuana (THC) in oral fluid at the following cut-off concentrations:

Test	Calibrator	Cut-off (ng/mL)
Cotinine (COT)	(-) Cotinine	30
Marijuana (THC)	Delta-9-Tetrahydrocannabinol	40

This test provides only a preliminary result. An alternative laboratory test must be used to confirm the results provided by this drug test. Liquid chromatography mass spectrometry (LC/MS) is the preferred method for the confirmation test.

The Healgen® Accurate Oral Fluid Drug Test is a competitive binding lateral flow immunochromatographic assay for the qualitative and simultaneous detection of Marijuana (THC) and Cotinine in human oral fluid at the cutoff concentrations listed below and their metabolites:

Test	Calibrator	Cut-off (ng/mL)
Cotinine (COT)	(-) Cotinine	30
Marijuana (THC)	Delta-9-Tetrahydrocannabinol	40

This assay provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography mass spectrometry (GC/MS) and liquid chromatography mass spectrometry (LC/MS) are the preferred confirmatory methods.

7. Device Description

The Healgen® Accurate Oral Fluid Drug Test COT/THC and Healgen® Accurate Oral Fluid Drug Test are immunochromatographic assays that uses a lateral flow system for the qualitative detection of cotinine and marijuana in human oral fluid. The tests are the first step in a two-step process. The second step is to send the sample for laboratory testing if preliminary positive results are obtained.

8. Substantial Equivalence Information

A summary comparison of features of the Healgen® Accurate Oral Fluid Drug Test COT/THC and the predicate devices are provided in following tables.

Table 1: Features Comparison of Healgen® Accurate Oral Fluid Drug Test COT/THC and the Predicate Device

Item	Device	Predicate – K223162
Indication(s) for Use	For the qualitative determination of cotinine and marijuana in human oral fluid.	Same
Calibrators	Cotinine and Delta-9-Tetrahydrocannabinol	Same
Methodology	Competitive binding, lateral flow immunochromatographic assays	Same
Type of Test	Qualitative	Same
Specimen Type	Human Oral fluid	Same
Cut-Off Values	COT 30 ng/mL THC 40 ng/mL	Same

Intended Use	For Over-The-Counter uses	For prescription uses

9. Test Principle

The Healgen® oral fluid drug test device is an immunoassay based on the principle of competitive binding. Drugs that may be present in the oral fluid specimen compete against their respective drug conjugates for binding sites on their specific antibody.

During testing, a portion of the oral fluid specimen migrates upward by capillary action. A drug, if present in the oral fluid specimen below its cut-off concentration, will not saturate the binding sites of its specific antibody. The antibody will then react with the drug-protein conjugate and a visible colored line will show up in the test line region of the specific drug strip. The presence of drug above the cut-off concentration in the oral fluid specimen will saturate all the binding sites of the antibody. Therefore, the colored line will not form in the test line region.

A drug-positive oral fluid specimen will not generate a colored line in the specific test line region of the strip because of drug competition, while a drug-negative oral fluid specimen will generate a line in the test line region because of the absence of drug competition.

To serve as a procedural control, a colored line will always appear at the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

10. Performance Characteristics

1. Analytical Performance Clearance of candidate device is for addition of OTC claim. See analytical performance in predicate K223162.

2. Comparison Studies See studies in predicate K223162

3. Lay-user study

Layuser studies for the Healgen® Accurate Oral Fluid Drug Test COT/THC were performed at three testing sites. Total 160 layusers with diverse educational and professional backgrounds performed tests based on the product insert. 160 lay users each received a spiked oral fluid sample to test with the Healgen Accurate Oral Fluid Drug Test device. Then, the same 160 lay users were paired up and received another Healgen Accurate Oral Fluid Drug Test device to test each other, for a total of 80 pairs of lay users and 160 tests. The spiked samples and 160 real samples were tested by LC/MS and results were compared with the lay user results. Additional layuser study was performed for THC at another testing site. Total 98 layusers with diverse educational and professional backgrounds performed tests based on the product insert. All results are presented in the tables below.

THC Spiked Samples

Concentrations / Results	-100% cut off	-75% cut off	-50% cut off	-25% cutoff	+25% cut off	+50% cut off	+75% cut off	+100% cut off
LC-MS (ng/Ml)	0.00	9.5	20.7	30.2	51.4	59.2	68.3	81.5
Negative	20	20	20	19	0	0	0	0
Positive	0	0	0	1	20	20	20	20
Total	20	20	20	20	20	20	20	20
Agreement (%)	100%	100%	100%	95%	100%	100%	100%	100%

COT Spiked Samples

Concentrations / Results	-100% cut off	-75% cut off	-50% cut off	-25% cutoff	+25% cut off	+50% cut off	+75% cut off	+100% cut off
LC-MS (ng/Ml)	0.0	7.5	15.4	22.3	38.1	45.4	53.4	60.9
Negative	20	20	20	20	0	0	0	0
Positive	0	0	0	0	20	20	20	20

Concentrations / Results	-100% cut off	-75% cut off	-50% cut off	-25% cutoff	+25% cut off	+50% cut off	+75% cut off	+100% cut off
Total	20	20	20	20	20	20	20	20
Agreement (%)	100%	100%	100%	100%	100%	100%	100%	100%

THC Real Samples

Drug Concentration	Number of Negative	Number of Positive	Total	The percentage of correct results
Drug free	155	0	155	100%
＜-50% Cut off	8	0	8	100%
-50% Cut off～Cut off	17	1	18	94.4%
Cut off～+50% Cut off	5	33	38	86.8%
＞+50% Cut off	0	39	39	100%

COT Real Samples

Drug Concentration	Number of Negative	Number of Positive	Total	The percentage of correct results
Drug free	45	0	45	100%
＜-50% Cut off	13	0	13	100%
-50% Cut off～Cut off	17	2	19	89.5%
Cut off～+50% Cut off	1	12	13	92.3%
＞+50% Cut off	0	70	70	100%

Layusers were given surveys on the ease of understanding the instruction for use. All layusers indicated that the device instruction is easy to understand and follow. A Flesch-Kincaid reading analysis was performed on the package insert and the scores revealed a reading Grade Level of 7.

3. Clinical Studies

Not applicable.

11. Conclusion

Based on the test principle and performance characteristics of the device, it's concluded that the Healgen® Accurate Oral Fluid Drug Test THC is substantially equivalent to the predicate.