June 10, 2026

DNA Genotek, Inc.
Jonathan Chan
Regulatory Affairs Program Manager
3000 - 500 Palladium Dr., Ottawa, Ontario K2V 1C2 CAN

Re: K254121
Trade/Device Name: Colli-Pee•Dx Urine Collection Kit
Regulation Number: 21 CFR 866.2920
Regulation Name: Device for home collection and transportation of clinical specimens by lay users for infectious disease testing
Regulatory Class: Class II
Product Code: SIH
Dated: December 19, 2025
Received: December 19, 2025

Dear Jonathan Chan:

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 13485 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 and process controls (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,

HIMANI BISHT -S

Himani Bisht, Ph.D.
Branch Chief
Division of Microbiology 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)*
K254121

Device Name
Colli-Pee™ •Dx Urine Collection Kit

Indications for Use *(Describe)*
The Colli-Pee™ •Dx Urine Collection Kit is a device for the self-collection of first-void urine for the purpose of collecting and transporting specimens for use in an FDA cleared STI molecular assay with which the device has been validated. Colli-Pee™•Dx Urine Collection Kit can be used at-home or in any private setting.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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DNAgenotek

510(k) Summary

This summary of the 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1900 and CFR 807.92.

Date:	10 June 2026
510(k) Number	K254121
Submitter:	DNA Genotek Inc. 3000 – 500 Palladium Drive, Ottawa, Ontario K2V 1C2 Canada
Contact:	Jonathan Chan, Regulatory Affairs Program Manager Tel: (613) 723-5757 Ext. 2438 Email: jonathan.chan@dnagenotek.com
Device Proprietary Name:	Colli-Pee™•Dx Urine Collection Kit
Device model:	N00399M
Common name:	At-home urine collection kit for sexually transmitted infection testing use
Proposed Device:	Regulation: 21 CFR 866.2920 (Device for home collection and transportation of clinical specimens by lay users for infectious disease testing) Panel: Microbiology (83) Classification: Class II Product Code: SIH (Device for home collection and transport of specimens by lay users for use in a cleared non-viral STI molecular assay)
Predicate Device:	Teal Wand (DEN240045) Regulation: 21 CFR 866.2920 (Device for home collection and transportation of clinical specimens by lay users for infectious disease testing) Panel: Microbiology (83) Classification: Class II Product Code: SEP (Device for home collection and transport of vaginal specimens by lay users for use in an approved HPV molecular assay)

1. INTENDED USE/INDICATIONS FOR USE

1.1. Intended Use

The Colli-Pee™•Dx Urine Collection Kit is a device for the self-collection of first-void urine for the purpose of collecting and transporting specimens for use in an FDA cleared STI molecular assay with which the device has been validated. Colli-Pee™•Dx Urine Collection Kit can be used at-home or in any private setting.

1.2. Indications for use

See Intended Use, above.

1.3. Special conditions for use statement

Rx - For Prescription Use Only

Performance characteristics of this device have only been validated with the cobas® CT/NG (K173887) and cobas® TV/MG (K190433).

2. DEVICE DESCRIPTION

The Colli-Pee™•Dx Urine Collection Kit enables the standardized, volumetric collection of first-void urine and sample stabilization. Samples collected at home or in any private setting are mailed to a laboratory for testing. In the laboratory, the urine sample is tested using an FDA cleared STI molecular assay with which the device has been validated. The Colli-Pee™•Dx Urine Collection Kit has been validated with the cobas® CT/NG and cobas® TV/MG. The Colli-Pee™•Dx Urine Collection Kit is single use and must be prescribed by a medical provider.

Device Components

The Colli-Pee™•Dx Urine Collection Kit consists of:

1) Colli-Pee™•Dx device
    a. Funnel
    b. Specimen tube and cap with 0.67 mL of stabilizing liquid
    c. Instructions for Use
2) Return instructions card
3) Bubble bag
4) Bio-specimen bag
5) Mailer box
6) Mailing materials (supplied by the test provider)

3. SUBSTANTIAL EQUIVALENCE INFORMATION

Table 1 outlines the similarities and differences between the predicate and proposed device.

Table 1. Comparison between Primary Predicate and Proposed devices

Device & Predicate Device(s):	K251440	DEN240045
Device Trade Name	Colli-Pee™•Dx Urine Collection Kit	Teal Wand
General Device Characteristic Similarities		
Intended Use/Indications For Use	The Colli-Pee™•Dx Urine Collection Kit is a device for the self-collection of first-void urine for the purpose of collecting and transporting specimens for use in an FDA cleared STI molecular assay with which the device has been validated. Colli-Pee™•Dx Urine Collection Kit can be used at-home or in any private setting.	The Teal Wand is a device for the self-collection of vaginal specimens for the purpose of collecting and transporting specimens for use in an FDA approved HPV molecular assay with which the collection device has been validated. The Teal Wand can be used at-home or in any private setting. Specimens can be collected, stored, and shipped dry in an empty vial.
Conditions for Use	At-home or any private setting by prescription only	Same
General Device Characteristic Differences		
Specimen Type	Urine	Vaginal swab

Principle of Operation	Sample collection by urinating through a funnel connected to a collection tube with stabilizing liquid	Sample collection by inserting device into vaginal opening and placing collection sponge into empty vial
Specimen Transport	Transported in a collection tube with stabilizing liquid	Transported dry in an empty vial
Validated Assay(s)	cobas® CT/NG and cobas® TV/MG	cobas® HPV

4. NON-CLINICAL PERFORMANCE CHARACTERISTICS

4.1. Precision

A precision study was conducted using three lots of the Colli-Pee™•Dx Urine Collection Kit. Negative male and female urine matrix co-spiked with *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoeae* (NG) was added to Colli-Pee™•Dx devices. Samples were spiked at concentrations representative of low- and high-positive samples. Analyte-negative male and female urine samples were also included. All samples tested using the cobas® CT/NG assay produced the expected results at baseline and following test conditions.

4.2. Shelf-life Stability

The Colli-Pee™•Dx Urine Collection Kits underwent stability testing following exposure to real-time aging conditions to support a shelf-life of 12 months. For real-time aging, the Colli-Pee™•Dx devices were stored at temperatures flanking the labeled storage temperature of 15°C to 30°C/59°F to 86°F. At each study time point, functional (cobas® CT/NG and cobas® TV/MG assays), chemical and physical (pH, Refractive Index, chemistry visual inspection, evaporation and visual inspection of plastics/labels/pouch) endpoints were evaluated in three (3) lots of devices at baseline and following exposure to the various test conditions. For functional performance testing, male and female negative urine matrix co-spiked CT and NG or *Trichomonas vaginalis* (TV) and *Mycoplasma genitalium* (MG) at concentrations representative of low-positive samples and analyte-negative samples were added to the aged Colli-Pee™•Dx devices and tested. A subset of devices containing co-spiked urine samples were subsequently stored at 32°C for 33 days to evaluate stability of the microorganisms in the aged devices. Study results showed that the Colli-Pee™•Dx devices performed as expected, with the results supporting a shelf-life of 12 months.

4.3. Sample Stability

A sample stability study was conducted using replicates of analyte-negative male and female urine samples and positive samples (male and female negative urine matrix co-spiked with either CT and NG or TV and MG at concentrations representative of low-positive and/or high-positive samples). The study evaluated the Colli-Pee™•Dx Urine Collection Kit performance for sample shipping and laboratory storage stability under the following test conditions:

- Simulated summer and winter transport profile cycling conditions (-10°C to 40°C/14°F to 104°F) representing extreme cold and hot temperatures for durations anticipated during a 130-hour (5-day) shipping period from the time of sample collection to receipt at the testing laboratory.
- Simulated summer and winter transport followed by 30 days of storage in the laboratory at temperatures (2°C to 30°C/36°F to 86°F)

At the study timepoints, both positive and negative sample in multiple replicates were tested with cobas® CT/NG and/or cobas® TV/MG assays. Expected results were obtained for all negative and positive samples at all conditions.

4.4. Detection Limit

The Limit of Detection (LoD) for CT, NG, TV and MG was determined using representative target microorganisms in pooled negative male and female urine, collected in Colli-Pee™•Dx Urine Collection Kit and then tested with the cobas® CT/NG and cobas® TV/MG assays, respectively. For the preliminary LoD, five independent replicates were co-spiked with either CT/NG or TV/MG across a range of five concentrations. The LoD was confirmed by testing 20 replicates at the preliminary LoD for each microorganism to determine the concentration that gave positive test results in ≥95% of the samples (at least 19/20 replicates testing positive for each strain). Results are shown in Table 2.

Table 2. LoD of CT, NG, TV and MG in Negative Clinical Urine Matrix

Colli-Pee™•Dx	CT	NG	TV	MG
Male	10 IFU/mL	0.25 CFU/mL	0.5 cells/mL	3 cp/mL
Female	2 IFU/mL	0.25 CFU/mL	0.5 cells/mL	3 cp/mL

4.5. Interfering Substances

A study was performed to evaluate whether relevant endogenous and exogenous substances, including substances commonly used by lay users at home or in any private settings may interfere with the detection of CT, NG, TV and MG using Colli-Pee™•Dx collected urine samples. Both positive and negative urine samples were tested with and without the potential interfering substances. The positive samples were prepared using male and female negative urine matrix co-spiked with low concentrations of CT and NG or TV and MG. Substances tested are described in Tables 3 and 4. The indicated concentrations represent the tested concentration of a substance, when assessed with the cobas® CT/NG and cobas® TV/MG assays, that did not result in interference. For additional interfering substance study data, refer to K173887 and K190433.

Table 3. Interfering Substances Study Results with cobas® CT/NG assay.

Test substance	Concentration without Interference
Low pH	4
High pH	9
Protein	0.5% (w/v)*
Blood	1% (w/v)*
Mucus	0.5% (w/v)
Summer's Eve Deodorant	0.25% (w/v)
Vagisil Deodorant	0.25% (w/v)
Vagisil Feminine Powder	0.25% (w/v)
Monistat Vaginal Cream	0.25% (w/v)
Vagisil Vaginal Cream	0.25% (w/v)
RepHresh Vaginal Gel	0.25% (w/v)
Gynalac Vaginal Gel	0.25% (w/v)
CeraVe Lotion	0.1% (w/v)
Purell Hand Sanitizer	0.1% (w/v)
Zytec Hand Sanitizer	0.1% (w/v)
Soft Soap Hand Soap	0.001% (w/v)
Dial Hand Soap	0.001% (w/v)
Banana Boat Sunscreen	0.1% (w/v)
Coppertone Sunscreen	0.1% (w/v)
Water	10% (w/v)

*Interference was observed at concentrations above this level.

Table 4. Interfering Substances Study Results with cobas® TV/MG assay.

Test substance	Concentration without Interference
Low pH	4
High pH	9
Protein	0.5% (w/v)
Blood	5% (w/v)
Mucus	0.5% (w/v)
Summer's Eve Deodorant	0.1% (w/v)
Vagisil Deodorant	0.1% (w/v)
Vagisil Feminine Powder	0.1% (w/v)
Monistat Vaginal Cream	0.1% (w/v)
Gynalac Vaginal Gel	0.1% (w/v)
CeraVe Lotion	0.1% (w/v)
Purell Hand Sanitizer	0.1% (w/v)
Zytec Hand Sanitizer	0.1% (w/v)
Soft Soap Hand Soap	0.001% (w/v)
Dial Hand Soap	0.001% (w/v)
Banana Boat Sunscreen	0.1% (w/v)
Coppertone Sunscreen	0.1% (w/v)
Water	10% (w/v)

4.6. Colli-Pee™•Dx Urine Collection Kit Robustness

To demonstrate Colli-Pee™•Dx Urine Collection Kit robustness, kits were challenged under the following conditions and low-positive and negative samples were tested with cobas® CT/NG or cobas® TV/MG assays:

- Urine collection volume variability
- Insufficient mixing of the specimen with stabilizing liquid

Across all testing conditions, expected results were obtained.

To demonstrate that Colli-Pee™•Dx Urine Collection Kit can withstand shipping without affecting product integrity, the kits were challenged and tested in accordance with ASTM D4169 standard testing, and the packages and components within the kit were inspected for damage after challenge. After undergoing drop, compression, and vibration testing no damage was found, with the results demonstrating the mechanical robustness of the Colli-Pee™•Dx Urine Collection Kit.

4.7. Usability and User Comprehension

Device usability and user comprehension was assessed to demonstrate the safety and effectiveness of the Colli-Pee™•Dx Urine Collection Kit for the at-home self-collection of first-void urine. The study was designed to simulate a workflow of the at-home self-collection of urine for testing on the cobas® CT/NG and cobas® TV/MG assays. Users were mailed the Colli-Pee™•Dx Urine Collection Kit, instructed to self-collect a urine specimen and mail the sample back to a testing laboratory. The study population of 219 naïve users included male and female participants ages 14 years and older, across different education levels and demographic groups representative of the U.S. general population. Usability study results demonstrated high user comprehension and ability to execute procedural steps across study participants.

4.8. Hazard Analysis and Mitigations

A comprehensive hazard analysis of the Colli-Pee™•Dx Urine Collection Kit was conducted in accordance with ISO 14971:2019, to identify known and foreseeable hazards and hazardous situations and ensure that their risks are appropriately assessed and controlled when used under the conditions of intended use. Specific risks associated with human factors, sample and device handling, storage, and environmental factors were evaluated. Risk control measures have been implemented to reduce the risks.

4.9. Frequently Asked Questions

A Frequently Asked Questions (FAQ) section has been included for lay users to provide educational information regarding the safety, benefit, and precautions of self-collection.

4.10. Biocompatibility

Biocompatibility risk assessment for the different housing components for the Colli-Pee™•Dx Urine Collection Kit and chemical toxicity assessment evaluating the worst-case exposure of the chemicals in the stabilizing liquid was conducted and yielded acceptable results.

5. CLINICAL PERFORMANCE CHARACTERISTICS

5.1. Clinical Studies

The clinical performance of the Colli-Pee™•Dx Urine Collection Kit is supported by the following datasets:

The clinical performance for male and female urine was established in K173887 and K190433 and data were leveraged based on the established equivalence.

A separate prospective clinical study was conducted, enrolling female participants, to support the performance of the Colli-Pee™•Dx Urine Collection Kit for use with cobas® CT/NG and cobas® TV/MG assays. Female participants (n=1357) were enrolled at 11 enrollment sites across the US between November 3, 2025, and April 9, 2026. Each participant self-collected three specimens in simulated home environment following respective instructions for use: a urine specimen collected using the FDA-cleared on-label urine collection kit, a urine specimen collected using the Colli-Pee™•Dx Urine Collection Kit, and a vaginal swab specimen collected using the FDA-cleared on-label kit. All specimens were tested per cobas® CT/NG and cobas® TV/MG assay instructions. The Colli-Pee™•Dx Urine Collection Kit performance was calculated by comparing each urine collection device result to the paired vaginal swab result to determine the ratios (Colli-Pee™•Dx Urine Collection Kit : on-label urine collection kit) of Positive Percent Agreement (PPA) and Negative Percent Agreement (NPA). The performance for each analyte is summarized in Table 5.

Table 5. Ratios of Agreement with the Vaginal Swab Specimens for the Colli-Pee™•Dx Urine Collection Kit as Compared to the FDA Cleared On-Label Urine Collection Kit.

Target Analyte	Ratio of Positive Percent Agreement (PPA)	Ratio of Negative Percent Agreement (NPA)
CT	1.027 (95% CI: 0.973, 1.081)	1.000 (95% CI: 0.998, 1.002)
NG	0.947 (95% CI: 0.847, 1.048)	1.000 (95% CI: N/A*)
TV	1.046 (95% CI: 0.993, 1.100)	0.998 (95% CI: 0.992, 1.004)
MG	1.103 (95% CI: 0.980, 1.226)	1.004 (95% CI: 0.998, 1.010)

*95% CI by normal approximation is not available.

6. CONCLUSION

The results from the studies submitted in this premarket notification demonstrate that the Colli-Pee™•Dx Urine Collection Kit is substantially equivalent to the predicate device.