October 27, 2022

DNA Genotek Inc.
Jonathan Chan
Senior Regulatory Affairs Specialist
3000 - 500 Palladium Drive
Ottawa, Ontario, K2V 1C2 Canada

Re: K212745
Trade/Device Name: ORAcollect®•Dx
Regulation Number: 21 CFR 862.1675
Regulation Name: Blood Specimen Collection Device
Regulatory Class: Class II
Product Code: OYJ
Dated: July 18, 2022
Received: July 21, 2022

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 (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 located 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.

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

803) for devices or postmarketing safety reporting (21 CFR 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 systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

Paula Caposino, Ph.D.
Acting Deputy Director
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
k212745

Device Name
ORAcollect®•Dx

Indications for Use *(Describe)*
ORAcollect®•Dx is intended for the collection of saliva samples for diagnostic testing of human DNA. Saliva samples may be collected by a healthcare professional or non-healthcare professional, such as a lay user. Saliva samples collected using ORAcollect®•Dx are stabilized and isolated for use in downstream diagnostic testing applications. Saliva samples collected using ORAcollect®•Dx can be transported and/or stored at ambient conditions.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

DNA genotek

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:	27 October 2022
510(k) Number	k212745
Submitter:	DNA Genotek Inc. 3000 – 500 Palladium Drive, Ottawa, Ontario K2V 1C2 Canada
Contact:	Jonathan Chan, Senior Regulatory Affairs Specialist Tel: (613) 723-5757 Ext. 2438 Email: jonathan.chan@dnagenotek.com
Device Proprietary Name Device models	ORAcollect®•Dx OCD-100, OCD-100A, OCD-100.014
Common names	Kit for collection of human DNA, Saliva kit, Sample collection kit for over-the-counter (direct-to-consumer) genetic testing use
Proposed Device Regulatory Classification	Regulation: 21CFR 862.1675 Blood specimen collection device Panel: Chemistry (75) Classification: Class II Product Code: OYJ DNA Specimen Collection, Saliva
Predicate Device	Oragene®•Dx (k192920) Regulation: 21CFR 862.1675 Blood specimen collection device Panel: Chemistry (75) Classification: Class II Product Code: OYJ DNA Specimen Collection, Saliva

Intended use

ORAcollect®•Dx is intended for the collection of saliva samples for diagnostic testing of human DNA. Saliva samples may be collected by a healthcare professional or non-healthcare professional, such as a lay user. Saliva samples collected using ORAcollect®•Dx are stabilized and isolated for use in downstream diagnostic testing applications. Saliva samples collected using ORAcollect®•Dx can be transported and/or stored at ambient conditions.

Indications for use

See Intended Use, above.

Special conditions for use statement

- ORAcollect®•Dx saliva samples can be self-collected.
- ORAcollect®•Dx devices are intended for use in over-the-counter (direct-to-consumer) downstream diagnostic testing applications.
- Test manufacturers must validate the use of ORAcollect®•Dx for their specific indications for use.
- ORAcollect®•Dx is intended for collection and stabilization of human DNA from saliva, it is not intended for the collection and stabilization of RNA, protein, or hormones.
- ORAcollect®•Dx has only been validated for use with germline testing.
- For use in individuals 18 years of age and older.
- ORAcollect®•Dx (OCD-100.014) device is intended for use (direct-to-consumer) use with AlphaID™ At Home Genetic Health Risk Service.

DEVICE DESCRIPTION

ORAcollect®•Dx family of collection devices offers reliable collection, stabilization, transportation and long-term ambient temperature storage of human DNA from saliva. ORAcollect®•Dx devices are a minimally invasive alternative for collecting high quality and quantity DNA for use with prescription and over-the-counter (direct-to-consumer) diagnostic testing applications.

ORAcollect®•Dx consists of a collection tube containing a stabilizing liquid and a double ended cap with an integrated sponge used to collect a saliva sample. Using provided instructions for use, saliva collection can take place in a laboratory setting, physician's office, at home, or in the field. Untrained (naïve) or professional users can carry out saliva collection.

After saliva is collected, the stabilizing liquid is mixed with the sample. Upon contacting saliva cells, the stabilizing liquid lyses cellular and nuclear membranes to release and stabilize nucleic acids (DNA). Samples can be immediately processed, transported or stored for future use.

ORAcollect·Dx device pre-collection shelf life is 24 months at room temperature (15°C to 25°C) from the date of manufacture. Post collection, ORAcollect·Dx samples are stable at room temperature for up to 60 days. ORAcollect·Dx device and sample integrity are preserved during typical ambient transport and storage conditions.

ORAcollect®•Dx saliva collection devices are suitable for use with prescription and over-the-counter (direct-to-consumer) downstream diagnostic testing applications, systems or platforms. Test or assay manufacturers must validate the use of ORAcollect®•Dx for their specific indications for use. Using DNA obtained from an ORAcollect®•Dx sample, laboratory testing is performed on genotyping systems or platforms in a CLIA (Clinical Laboratory Improvement Amendments) certified laboratory.

To date, ORAcollect®•Dx collection device performance has been established with the following FDA cleared test systems:

eSensor® Warfarin Sensitivity Saliva Test (k152612)

The eSensor® Warfarin Sensitivity Saliva Test is an in vitro diagnostic for the detection and genotyping of the *2 and *3 alleles of the cytochrome P450 (CYP450) 2C9 gene locus and the Vitamin K epoxide reductase C1 (VKORC1) gene promoter polymorphism (-1639G>A) from genomic DNA extracted from

human saliva samples collected using the Oragene®·Dx and ORAcollect®·Dx devices, as an aid in the identification of patients at risk for increased warfarin sensitivity. For Prescription use only.

Progenika Biopharma A1AT Genotyping Test (k192858, k211115)

The Progenika A1AT genotyping kit is a quantitative, polymerase chain reaction (PCR) and hybridization-based in vitro diagnostic test to be used with the Luminex 200 instrument (with xPONENT software) for the simultaneous detection and identification of 14 allelic variants and their associated alleles found in the Alpha-1 antitrypsin (A1AT) codifying gene SERPINA1. The test intended for use with genomic DNA extracted from human whole blood samples collected as dry blood spot (DBS) or in K2-EDTA or from human saliva samples collected as buccal swabs using **ORAcollect·Dx (OCD-100)**. The A1AT allelic variant genotypes and associated allele results, when used in conjunction with clinical findings and other laboratory tests, are intended as an aid in the diagnosis of individuals with A1AT deficiency (A1ATD). The kit is indicated for prescription use only.

AlphaID™ At Home Genetic Health Risk Service (k221420)

The AlphaID™ At Home Genetic Health Risk Service uses qualitative genotyping to detect clinically relevant variants in genomic DNA isolated from human saliva collected from individuals ≥ 18 years old with the **ORAcollect·Dx (OCD-100.014)** for the purpose of reporting and interpreting genetic health risks. The service is intended to provide users with their genetic health risk linked to alpha-1antitrypsin deficiency (AATD). This information will help in their conversations with their healthcare professional.

Note: ORAcollect®·Dx (OCD-100.014) is a physically and chemically equivalent custom version of ORAcollect®·Dx (OCD-100). ORAcollect®·Dx (OCD-100.014) and is intended for use in the collection of saliva samples. Human DNA from the saliva sample is isolated, stabilized, and suitable for over-the-counter use with the AlphaID™ At Home Genetic Health Risk Service. Saliva samples collected using ORAcollect·Dx (OCD-100.014) are stabilized and can be transported and/or stored long-term at ambient conditions.

SUBSTANTIAL EQUIVALENCE INFORMATION

The following table outlines the similarities and differences between the predicate and proposed device.

Table 1. Comparison between Primary Predicate and Proposed devices

Principle, Materials and Technology	Oragene®•Dx *(predicate device – k192920)*	ORAcollect®•Dx (*proposed device – K212745)*	Similar	Different
Intended Use	Oragene®•Dx is intended for use in the non-invasive collection of saliva samples for *in vitro* diagnostic testing of human DNA. Saliva may be collected by spitting directly into the Oragene®•Dx container or may be transferred into the Oragene®•Dx container using a sponge. Saliva samples may be collected by a healthcare professional or non-healthcare professional, such as a lay user. Saliva samples collected using Oragene®•Dx are stabilized and isolated for use in downstream diagnostic testing applications. Saliva samples collected using Oragene®•Dx can be transported and/or stored long term at ambient conditions	ORAcollect®•Dx is intended for the collection of saliva samples for diagnostic testing of human DNA. Saliva samples may be collected by a healthcare professional or non-healthcare professional, such as a lay user. Saliva samples collected using ORAcollect®•Dx are stabilized and isolated for use in downstream diagnostic testing applications. Saliva samples collected using ORAcollect®•Dx can be transported and/or stored at ambient conditions.	X	
Special conditions for use	Prescription and Over-the-counter use	Prescription and Over-the-counter use	X	
Analyte	DNA	DNA	X	
Sample collection	Non-invasive collection of biological samples delivered into a non-sterile plastic collection tube	Non-invasive collection of biological samples delivered into a non-sterile plastic collection tube	X	
Formats/Models	Multiple: OGD-500, OGD-510, OGD-575, OGD-600, OGD-610, OGD-675	Multiple: OCD-100, OCD-100A, OCD-100.014	X	

Principle, Materials and Technology	Oragene®•Dx *(predicate device - k192920)*	ORAcollect®•Dx (*proposed device – k212745)*	Similar	Different
Tube material	Plastic	Plastic	X	
Sample source	Human saliva	Human saliva	X	
Additive	Nucleic acid stabilization solution	Nucleic acid stabilization solution	X	
Transport and Stability	Pre-collection Oragene®•Dx kits can be transported at temperatures ranging from -20°C to 50°C Post-collection Oragene®•Dx samples can be transported at temperatures ranging from -20°C to 50°C Pre-collection Oragene®•Dx kits can be stored at room temperature for up to 30 months Post-collection Oragene®•Dx samples can be stored at room temperature for up to 12 months	Pre-collection ORAcollect®•Dx kits can be transported at temperatures ranging from -20°C to 50°C Post-collection ORAcollect®•Dx samples can be transported at temperatures ranging from -20°C to 50°C Pre-collection ORAcollect®•Dx kits can be stored at room temperature for up to 24 months Post-collection ORAcollect®•Dx samples can be stored at room temperature for up to 60 days		X
Performance and suitability for use with molecular diagnostic applications	Performance of stabilized DNA used in molecular diagnostic testing has been established in k110701, k141410, k152556. Suitability of standard Oragene®•Dx instructions for use in a typical over-the-counter (direct-to- consumer) setting has been established (k192920)	Performance of stabilized DNA used in prescription and over-the-counter(direct-to-consumer) molecular diagnostic testing has been established with • eSensor® Warfarin Sensitivity Saliva Test (k152464, k152612). • Progenika Biopharma A1AT Genotyping Test (k192858, k211115) • AlphaID™ At Home Genetic Health Risk Service (k221420)	X	
The similarities in intended use, materials, technological characteristics show that ORAcollect®•Dx (k212745) are substantially equivalent to the primary predicate Oragene®•Dx devices (k192920). The differences tabulated above do not affect the safety and performance of ORAcollect®•Dx devices.				

PERFORMANCE CHARACTERISTICS

Reproducibility/Precision

The reproducibility of the ORAcollect®•Dx (*device models: OCD-100, OCD-100A*) collection device has been previously evaluated (**see k152464)**. In addition, analytical precision of ORAcollect®•Dx collection device has been further demonstrated with the following FDA cleared test systems eSensor® Warfarin Sensitivity Saliva Test (**k152612**) and Progenika Biopharma A1AT Genotyping Test (**k192858, k211115**).

Stability

Pre-collection shelf-life

Pre-collection shelf-life of ORAcollect®·Dx devices has been previously evaluated and demonstrated (**see k152464**). ORAcollect®•Dx (device models: OCD-100, OCD-100) formats are FDA cleared and have of the same physical and chemical components including their instructions for use. Studies in k152464 supports that ORAcollect·Dx devices can be stored for 24 months at ambient, room temperature conditions or exposed to typical transport conditions, with no significant impact on performance.

Post-collection sample stability

Post-collection sample stability of ORAcollect®·Dx devices has been previously demonstrated (**see k152464**). ORAcollect®•Dx (device models: OCD-100, OCD-100) formats are FDA cleared and have of the same physical and chemical components including their instructions for use. Studies in k152464 supports that ORAcollect·Dx sample stability of 60 days at room temperature and stability upon exposure to conditions expected during typical transport (i.e. transient exposure to temperatures between -20°C and 50°C.

Detection Limit

User Study

The effects of sampling variability due to user collection error, incorrect collection methods and collection from an incorrect site were previously evaluated in **k152464**. Study data demonstrated the robustness of the ORAcollect·Dx collection device samples collected using the varied collected methods, incorrect collection methods or incorrect collection site even in the hands of naive users and/or when instructions for use are not followed properly.

Dry Mouth Study

The effect of dry mouth on the samples collected using the ORAcollect·Dx device was evaluated in **k152464**.

Human Factors

User compliance to ORAcollect®·Dx collection instructions and its impact on sample performance, as well as to identify areas of difficulty in the collection procedure was evaluated in **k152464**.

Limit of Detection

For limit of detection on Progenika Biopharma A1AT Genotyping Test, see **k211115**.

Interfering Substances

Endogenous Substances

The effect of potentially interfering endogenous substances on performance of saliva samples collected with the ORAcollect®·Dx device has been successfully demonstrated with the following FDA cleared test systems eSensor® Warfarin Sensitivity Saliva Test (k152612) and Progenika Biopharma A1AT Genotyping Test (k192858). There was no observable effect to performance of any of the potentially interfering endogenous substances.

Exogenous Substances

The effect of potentially interfering exogenous substances on the performance of saliva samples collected with the ORAcollect®·Dx devices have been demonstrated with the following FDA cleared test systems eSensor® Warfarin Sensitivity Saliva Test (k152612) and Progenika Biopharma A1AT Genotyping Test (k192858). There was no observable effect to performance of any of the potentially interfering exogenous substances.

Comparison Studies

Matrix Comparison

ORAcollect®·Dx is available in equivalent and identical formats OCD-100 and OCD-100A. The OCD-100A format includes a molded plastic insert inside the collection tube. The insert is intended to facilitate or enable a more efficient physical handling of the sample in the laboratory but has no impact on sample collection. Study data in k152464 indicates that the insert present in the OCD-100A format does not affect the performance of the device. ORAcollect®·Dx (OCD-100.014) is a physically and chemically equivalent custom version of ORAcollect®·Dx OCD-100. OCD-100.014 and is intended for use in the collection of saliva samples. Human DNA from the saliva sample is isolated, stabilized, and suitable for over-the-counter use with the AlphaID™ At Home Genetic Health Risk Service. Saliva samples collected using ORAcollect·Dx (OCD-100.014) are stabilized and can be transported and/or stored long-term at ambient conditions.

Method Comparison

Method comparison studies have been previously evaluated in k152612 and k192858. Genotyping results on the eSensor Warfarin Sensitivity Saliva Test were compared to results from the 'gold standard' bidirectional sequencing in order to assess performance.

Over-the-Counter (Direct-to-Consumer) Use

Performance of saliva samples collected with ORAcollect®·Dx (device model OCD-100.014) when used in an over-the-counter (direct-to-consumer) setting. The objective of the study was to demonstrate that donors comprehend the instructions for use provided with the ORAcollect®·Dx device and can successfully collect saliva samples acceptable for use in an over-the-counter (direct-to-consumer) setting. ORAcollect•Dx collection device was provided as part of the AlphaID™ Saliva Collection Kit which is intended to be used with the AlphaID™ At Home Genetic Health Risk Service.

Specifically, potential users enrolled in usability studies collected saliva samples at home using standard ORAcollect®•Dx devices instructions and mailed them to a testing laboratory as is typical in

a direct-to- consumer setting. Upon receipt at a certified CLIA testing laboratory, each study sample was assessed for compliance to collection instructions and sample volume, DNA concentration. The results of the user comprehension survey and the physical characteristics of the participant samples demonstrated that the ORAcollect®·Dx collection device can be used successfully in the direct-to-consumer setting.

CONCLUSION

The results from the studies submitted in this premarket notification are complete and demonstrate that the ORAcollect®•Dx device is substantially equivalent to the predicate device. The submitted information supports the use of the ORAcollect®•Dx devices for prescription and over-the-counter (direct-to-consumer) use with FDA cleared and legally marketed molecular diagnostics applications.