510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY

I Background Information:

A 510(k) Number

K212745

B Applicant

DNA Genotek Inc

C Proprietary and Established Names

ORAcollect®•Dx

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
OYJ	Class II	21 CFR 862.1675 - Blood Specimen Collection Device	CH - Clinical Chemistry

II Submission/Device Overview:

A Purpose for Submission:

Modification to an existing device

B Measurand:

Not applicable

C Type of Test:

Saliva collection for DNA testing

III Intended Use/Indications for Use:

A Intended Use(s):

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.

B Indication(s) for Use:

See Intended for Use above

C Special Conditions for Use Statement(s):

Models OCD-100 and OCD-100A

- 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.

Model OCD-100.014:

- ORAcollect®•Dx (Model OCD-100.014) collection device is only cleared for use with the AlphaID At Home Genetic Health Risk service.
- For use in individuals 18 years of age and older.

D Special Instrument Requirements:

None

IV Device/System Characteristics:

A Device Description:

ORAcollect®•Dx (models OCD-100A, OCD-100, and OCD-100.014) is a collection device for human saliva samples. All ORAcollect®•Dx formats have the same collection principle in that saliva is collected using a sponge into a collection tube containing a stabilizing liquid. All formats are made from the same physical and chemical materials. All formats consist of the same double ended tube cap with an attached integrated sponge, the same collection tube and contain the same DNA stabilizing liquid. The attached integrated sponge is used to collect and transfer the saliva sample from a donor's mouth into the stabilizing liquid inside the collection tube.

The model OCD-100A includes a molded plastic insert inside the collection tube. The insert does not impact user experience or user collection instructions but rather is intended to facilitate or

enable a more efficient physical handling of the sample in the laboratory. The model OCD-100.014 is identical to the OCD-100 but is labeled for use with a specific assay.

B Principle of Operation:

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.

V Substantial Equivalence Information:

A Predicate Device Name(s):
Oragene®•Dx

B Predicate 510(k) Number(s):
K192920

C Comparison with Predicate(s):

Device & Predicate Device(s):	K212745	K192920
Device Trade Name	ORAcollect®•Dx	Oragene®•Dx
General Device Characteristic Similarities		
Intended Use	Intended for use in the collection of saliva samples	Same
Indications For Use	For in vitro diagnostic testing of human DNA	Same
Sample Source	Human saliva	Same
Collection Service Contents	Nucleic acid stabilization solution	Same
General Device Characteristic Differences		
Device Design	Consists of a buccal swab in a device containing stabilizing liquid	Consists of a collection tube with a funnel lid attached that contains a stabilizing liquid
Formats/Models	OCD-100, OCD-100A, OCD-100.014	OGD-500, OGD-510, OGD-575, OGD-600, OGD-610, OGD-675

VI Standards/Guidance Documents Referenced:

Not applicable

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

   The reproducibility of the ORAcollect®•Dx collection device was established in K152464, K152612, and K192858.

2. Linearity:

   Not applicable

3. Analytical Specificity/Interference:

   The effects of endogenous and exogenous interfering substances were established in K152612 and K192858.

4. Assay Reportable Range:

   Not applicable

5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):

   Pre-collection stability of the collection device, stability of samples post-saliva collection, and freeze-thaw stability of samples stored in the ORAcollect®·Dx device was established in K152464.

6. Detection Limit:

   Sample volume tolerance studies were conducted in K152464.

7. Assay Cut-Off:

   Not applicable

B Comparison Studies:

1. Method Comparison with Predicate Device:
   Method comparison studies were previously performed in order to determine the accuracy of the genotype obtained on the eSensor Warfarin Sensitivity Saliva Test (K152612) and A1AT Genotyping Test (K192858) using saliva samples collected by ORAcollect®•Dx as compared to bi-directional DNA sequencing.

2. Matrix Comparison:

A matrix comparison study demonstrating equivalence between the different models was conducted in K152464.

C Clinical Studies:

1. Clinical Sensitivity:

Not applicable

2. Clinical Specificity:

Not applicable

3. Other Clinical Supportive Data (When 1. and 2. Are Not Applicable):

Evaluation of lay user collection and labeling comprehension:

Performance of saliva samples collected with ORAcollect®·Dx (device model OCD-100.014) was evaluated in an over-the-counter setting. The study consisted of samples from 389 subjects 18 years or older and the demographics were representative of the United States (US) population. Each participant completed the saliva sample collection following the instructions for use and mailed the collected sample to a testing laboratory. Each study sample was assessed for compliance to shipping instructions, collection instructions, sample volume, DNA concentration, and genotype calls. User comprehension of test instructions, including comprehension of sample collection instructions was also assessed. A sub-set of the study participants were randomly selected to complete the same process, excluding the completion of the user questionnaire to evaluate the possibility of questionnaire-related bias. Laboratory results (DNA concentration, yield and genotyping call rates) from those who completed the user questionnaire and those who did not were compared to identify any potential bias between the populations.

Two samples out of the 389 specimens were not evaluated, one due to insufficient volume (< 40µL), and another due to the lack of detectable DNA. The remaining 387 out of 389 samples (99.5%) contained the minimum amount of DNA after extraction, and were evaluated. Of these 387 samples, there were 2 “no calls” in the first pass (385/387 = 99.5% call rate in first pass). After the second pass, there was 1 “no call” and genotyping results for 386 out of 387 samples (99.7%) matched confirmatory sequencing. No bias was observed between the questionnaire and non-questionnaire groups. Genotyping results were confirmed via bi-directional sequencing.

The results of the user comprehension survey and the physical characteristics of the participant samples demonstrate that the ORAcollect®·Dx collection device can be used successfully in the over-the-counter setting.

A Flesch-Kincaid reading analysis was performed on the collection device labeling in K141410. Lay user collection and labeling comprehension for the ORAcollect®·Dx model

OCD-100.014 device, when used with the AlphaID At Home Genetic Risk Service was reviewed and found acceptable.

D Clinical Cut-Off:

Not applicable

E Expected Values/Reference Range:

Not applicable

VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

IX Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.