510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY

I Background Information:

A 510(k) Number

K192920

B Applicant

DNA Genotek Inc.

C Proprietary and Established Names

Oragene®•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):

See Indications for Use below.

B Indication(s) for 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.

C Special Conditions for Use Statement(s):

OTC - Over The Counter

Device manufacturers must validate the use of Oragene®•Dx for use with their device.

D Special Instrument Requirements:

None.

IV Device/System Characteristics:

A Device Description:

Oragene®•Dx (models OGD-500, OGD-510, OGD-575, OGD-600, OGD-610, and OGD-675) consists of a saliva collection tube with a funnel lid attached that contains a stabilizing liquid. Saliva is delivered directly by expectorating into the collection tube. A small cap is provided to close the tube for transport and storage. The difference in the six models is the amount and/or concentrations of the reagents in the tube, which vary because of the difference in the amount of saliva collected. The ratio of final sample to stabilizing liquid volume remains the same. The 600-series (OGD-600 and OGD-610) differs from the 500-series (OGD-510, and OGD-500) in labeling only (600 series labeling is in English only). The OGD-575 and OGD-675 models include a sponge for assisted collection of saliva.

Oragene-Dx can be used with both prescription use only and over-the-counter molecular diagnostic test systems.

B Principle of Operation:

Oragene®•Dx collects and stabilizes human DNA from saliva; it can also be used for the transportation and long-term room temperature storage of a sample. Oragene®•Dx is a non-invasive alternative for collecting DNA for use with molecular diagnostic applications.

The collection device (all models) consist of a collection tube with a funnel lid attached that contains a stabilizing liquid. Saliva is delivered directly by spitting into the collection tube. After saliva is collected, the stabilizing liquid is mixed with the sample. A small cap is provided to close the tube for transport and storage (funnel with lid is removed and discarded). Upon contacting saliva cells, the stabilizing liquid lyses cellular and nuclear membranes to release and

stabilize nucleic acids. Samples can be immediately processed, transported or stored for future use.

V Substantial Equivalence Information:

A Predicate Device Name(s):

Oragene®•Dx Collection Device, models OGD-500; OGD-575; OXD-525; OYD-500

B Predicate 510(k) Number(s):

K110701

C Comparison with Predicate(s):

Similarities		
Device & Predicate Device(s):	K192920	K110701
Intended Use	Intended for use in the non-invasive collection of saliva samples.	Same
Indications for use	For use in vitro diagnostic testing of human DNA	Same
Sample source	Human Saliva	Same
Collection Device Contents	Nucleic acid stabilization solution	Same
Differences		
Device & Predicate Device(s):	K192920	K110701
Tests intended for use with the saliva collection device	Downstream in vitro diagnostic tests of human germline DNA validated for use with the Oragene®•Dx	eSensor® Warfarin Sensitivity Saliva Test
Device model numbers	OGD-500, OGD-510, OGD-575, OGD0600, OGD-610, OGD-675	OGD-500, OGD-575, OXD-525; OYD-500

VI Standards/Guidance Documents Referenced:

- ISO 13485: Medical devices - Quality management systems — Requirements for regulatory purposes (2016)
- ISO 14971: Medical devices - Application of risk management to medical devices (2007)

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

The reproducibility of the Oragene®•Dx collection device was established in k110701 and k141410.

2. Linearity:

   Not applicable.

3. Analytical Specificity/Interference:

   The effect of endogenous and exogenous interfering substances was established in k110701 and k141410.

4. Assay Reportable Range:

   Not applicable.

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

   Pre-collection shelf-life stability of the collection device, stability of samples post-saliva collection, and freeze-thaw stability of samples stored in the Oragene®•Dx collection device was established in k110701.

6. Detection Limit:

   Sample volume tolerance studies were conducted in k110701.

7. Assay Cut-Off:

   Not applicable.

B Comparison Studies:

1. Method Comparison with Predicate Device:

   A method comparison study was previously performed in order to determine the accuracy of the genotype obtained on the eSensor® Warfarin Sensitivity Saliva Test (k110786) using saliva samples collected by the Oragene•Dx collection device as compared to bi-directional DNA sequencing in k110786.

2. Matrix Comparison:

   A matrix comparison study was conducted in k110701.

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: A study to evaluate the lay user collection and labeling comprehension of the Oragene•Dx OGD-610 model was performed by over the counter users. The study consisted of 206 subjects 18 years or older and the demographics were representative of the US population. Participants independently collected a saliva sample at home using the instructions for use, answered the user comprehension questionnaire, and mailed both components according to the study instructions. Upon receipt at the testing laboratory, each study sample was assessed for compliance to collection instructions, sample volume, DNA concentration, and sequencing quality control metrics. User comprehension of test instructions, including comprehension of sample collection instructions was also assessed.

Of the samples evaluated, 97.35% contained the minimum amount of DNA required for testing after DNA extraction. Samples from two individuals were re-extracted from a second aliquot, for a total of 98.41% containing the minimum amount of DNA required for testing, demonstrating that customers were able to follow sample collection instructions in an over the counter setting to obtain adequate sample for testing.

A Flesch-Kincaid reading analysis was performed on the collection device labeling in k141410. Lay user collection and labeling comprehension for the Oragene•Dx OGD-500.001 device, when used with the over-the-counter 23andMe PGS Carrier Screening Test, was previously evaluated in k141410.

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.