

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY TEMPLATE**

A. 510(k) Number:

k152556

B. Purpose for Submission:

Modification to an existing device

C. Measurand:

Not applicable

D. Type of Test:

Saliva Collection for DNA testing.

E. Applicant:

DNA Genotek Inc.

F. Proprietary and Established Names:

Oragene®•Dx, models OGD-510, OGD-600, OGD-610, and OGD-675

G. Regulatory Information:

1. Regulation section:

21 CFR §862.1675 – Blood specimen collection device

2. Classification:

Class II

3. Product code:

OYJ – DNA specimen collection, saliva

4. Panel:

Chemistry (75)

H. Intended Use:

1. Intended use(s):

See indications for use below.

2. Indication(s) for use:

Oragene•Dx is intended for use in the non-invasive collection of saliva samples. DNA from the saliva sample is isolated, stabilized, and suitable for use in FDA cleared molecular diagnostic applications. 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 collected using Oragene•Dx are stabilized and can be transported and/or stored long term at ambient conditions.

3. Special conditions for use statement(s):

For prescription use.

For use in people 18 years of age or older.

The Oragene Dx collection devices are only cleared for use with genotyping tests that have obtained FDA clearance for use with saliva samples obtained with these collection devices.

4. Special instrument requirements:

None.

I. Device Description:

Oragene•Dx device formats OGD-510, OGD-600, OGD-610 and OGD-675 consist of a collection tube, a DNA stabilizing liquid and optional sponges for assisted collection. These Oragene•Dx device formats are made from the same physical and chemical materials as the Oragene•Dx formats cleared in k110701. Oragene•Dx format OGD-510 differs from OGD-500, cleared in k110701, in the amount of DNA stabilizing liquid in the tube and in the amount of saliva to be collected; The ratio of final sample to stabilizing liquid volume remains the same. Oragene•Dx device formats in the 600-series (OGD-600, OGD-610 and OGD-675) differ from their OGD-500 series counterparts (OGD-510, and OGD-500, OGD-575 cleared in k110701) in labeling only (600 series labeling is in English only).

J. Substantial Equivalence Information:

1. Predicate device name(s):

Oragene® Dx collection device, models OGD-500, OGD-575, OXD-525, and OYD-500

2. Predicate 510(k) number(s):
k110701

3. Comparison with predicate:

Principle, Materials and Technology	Predicate device Oragene·Dx: OGD-500 (k110701)	Subject device Oragene·Dx: OGD-510,
<u>Similarities</u>		
Intended Use	Oragene·Dx is intended for use in the non-invasive collection of saliva samples. DNA from the saliva sample is isolated, stabilized, and suitable for use in FDA cleared molecular diagnostic applications. 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 collected using Oragene·Dx are stabilized and can be transported and/or stored long term at ambient conditions.	Same as predicate
Analyte	DNA	Same as predicate
Device physical design	Consists of a collection tube, a DNA stabilizing liquid and optional sponges for assisted collection.	Same as predicate
Sample collection	Non-invasive collection of biological samples delivered into a non-sterile plastic collection tube	Same as predicate
Tube material	Plastic	Same as predicate
Sample source	Human saliva	Same as predicate
Performance	Performance has been established with the	Same as predicate

	eSensor® Warfarin Sensitivity Saliva Test	
Stability	24 months at room temperature; 12 months at -20±5°C and 6±4°C	Same as predicate
Post-collection sample stability	12 months at room temperature, -20±5°C or 6±4°C; 3 months at 50±5°C	Same as predicate
<u>Differences</u>		
Sample volume	2 milliliters	1 milliliter
Volume of DNA stabilizer	2 milliliters	1 milliliter

Principle, Materials and Technology	Predicate devices Oragene·Dx: OGD-500 and OGD-575 (k110701)	Subject devices Oragene·Dx: OGD-600, OGD-610 and OGD-675
<u>Similarities</u>		
Intended Use	Oragene·Dx is intended for use in the non-invasive collection of saliva samples. DNA from the saliva sample is isolated, stabilized, and suitable for use in FDA cleared molecular diagnostic applications. 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 collected using Oragene·Dx are stabilized and can be transported and/or stored long term at ambient conditions.	Same as predicate
Analyte	DNA	Same as predicate
Device physical	Consists of a collection tube, a DNA stabilizing	Same as predicate

design	liquid and optional sponges for assisted collection.	
Sample collection	Non-invasive collection of biological samples delivered into a non-sterile plastic collection tube	Same as predicate
Tube material	Plastic	Same as predicate
Sample source	Human saliva	Same as predicate
Performance	Performance has been established with the eSensor® Warfarin Sensitivity Saliva Test	Same as predicate
Stability	24 months at room temperature; 12 months at $-20\pm 5^{\circ}\text{C}$ and $6\pm 4^{\circ}\text{C}$	Same as predicate
Post-collection sample stability	12 months at room temperature, $-20\pm 5^{\circ}\text{C}$ or $6\pm 4^{\circ}\text{C}$; 3 months at $50\pm 5^{\circ}\text{C}$	Same as predicate
<u>Difference</u>		
Labeling	Mutiple languages	English

K. Standard/Guidance Document Referenced (if applicable):

ISO 13485: Medical Device – Quality Management Systems

ISO 14971: Medical Device – Application of Risk Management in Medical Devices

L. Test Principle:

The Oragene Dx collection device models OGD-510, OGD-600, OGD-610, and OGD-675 collect and stabilize DNA from human saliva; they can also be used for the transportation and long-term room temperature storage of a sample. These Oragene•Dx models are for collecting DNA for use in molecular diagnostic applications that are cleared for use with the Oragene•Dx collection device.

Saliva can be delivered directly into the Oragene Dx collection device by spitting or indirectly using provided sponges to transfer saliva into the device. The collected saliva sample is mixed with a stabilizing liquid in the device, and upon contacting cells in the saliva, 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. DNA extraction from Oragene•Dx can be performed using alcohol precipitation or other methods for the purpose of molecular diagnostic applications.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

This submission is for four different formats of the saliva collection tube. Three of those tubes, 600, 610, and 675 are identical in specifications as those cleared in k110701, the only difference being the languages on the package insert. The new version will have English only labeling. The fourth tube, OGD-510, is a new format and the performance testing in this submission was performed on that model of tube. The other tube types were not re-evaluated.

a. *Precision/Reproducibility:*

No new reproducibility studies were necessary to support clearance of the modified device. The reproducibility of the Oragene·Dx collection device was evaluated in **k110701**.

b. *Linearity/assay reportable range:*

Not applicable.

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*

See the decision summary for k110701.

d. *Detection limit:*

Detection limit and sample volume tolerance studies were conducted in k110701, and the detection limit and sample volume tolerance remains unchanged.

e. *Analytical specificity:*

The effect of endogenous and exogenous interfering substances was evaluated in k110701 and remains unchanged.

f. *Assay cut-off:*

Not applicable.

2. Comparison studies:

a. *Method comparison with predicate device:*

A study was performed to evaluate the Oragene Dx collection device OGD-510. A total of 45 donors were asked to collect saliva using the predicate (OGD-500) and subject (OGD-510) collection devices. All samples were obtained and 90 samples were analyzed for DNA concentration, yield and A260/A280 ratios and 90 tests were performed on the eSensor Warfarin Sensitivity Saliva Test.

All samples collected from the two formats in the comparison study yielded DNA concentrations of 2 ng/μl or better and a total DNA yield of 10 ng (0.010 μg) or better. 100% of the samples met the A260/A280 criteria of 1.2 – 2.3.

The candidate device, OGD-510, generated samples where 100% generated correct calls with the eSensor Warfarin Sensitivity test in one run.

b. Matrix comparison:

Matrix comparison studies for the different tube type formats were previously conducted for Oragene Dx devices with the eSensor Warfarin Saliva Test in k110786 and remain unchanged.

3. Clinical studies:

a. Clinical Sensitivity:

Not applicable.

b. Clinical specificity:

Not applicable.

c. Other clinical supportive data (when a. and b. are not applicable):

Not applicable.

4. Clinical cut-off:

Not applicable.

5. Expected values/Reference range:

Not applicable.

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

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