DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

May 26, 2016

DNA GENOTEK, INC.
DAN FULLERTON
2 BEAVERBROOK ROAD
OTTAWA, ONTARIO K2K 1L1
CANADA

Re: k152556
Trade/Device Name: Oragene•Dx OGD-510, Oragene•Dx OGD-600, Oragene•Dx OGD-610, Oragene•Dx OGD-675
Regulation Number: 21 CFR §862.1675
Regulation Name: Blood specimen collection device
Regulatory Class: II
Product Code: OYJ
Dated: April 19, 2016
Received: April 21, 2016

Dear Mr. Fullerton:

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. 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 Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney H. Lias -S

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K152556

Device Name
Oragene·Dx: OGD-510; OGD-600; OGD-610; OGD-675

Indications for Use *(Describe)*
Oragene·Dx devices are intended for use in the non-invasive collection of saliva samples. Human 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.

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.

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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:	18 April 2016
Submitter:	DNA Genotek Inc. 3000 – 500 Palladium Drive, Ottawa, Ontario K2V 1C2 Canada
Contact:	Dan Fullerton Vice President Operations, Quality & Regulatory Affairs Tel: (613) 723-5757 Ext. 213, Fax: (613) 368-4628 Email: dan.fullerton@dnagenotek.com
Device Proprietary Name	Oragene®•Dx Format: OGD-510, OGD-600, OGD-610, OGD-675
Common names	Kit for collection of human DNA, Saliva kit, Sample collection kit
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 Regulatory Classification	Oragene·Dx OGD-500 (k110701) Regulation: 21CFR 862.1675 Blood specimen collection device Panel: Chemistry (75) Classification: Class II Product Code: OYJ DNA Specimen Collection, Saliva

INTENDED USE

Intended use

Oragene·Dx devices are intended for use in the non-invasive collection of saliva samples. Human 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.

Indications for use

See Intended Use, above.

Special conditions for use statement

For prescription use.

DEVICE DESCRIPTION

The Oragene·Dx family of products offers reliable collection, stabilization, transportation and long-term room temperature storage of human DNA from saliva. Oragene·Dx is a non-invasive alternative for collecting high quality and quantity DNA for use in molecular diagnostic applications. Oragene·Dx is a device family available in multiple device formats or models.

Oragene·Dx device formats OGD-510, OGD-600, OGD-610 and OGD-675, have the same collection principle and intended use as the FDA cleared Oragene·Dx formats (k110701). All Oragene·Dx formats consist of a collection tube, a DNA stabilizing liquid and optional sponges for assisted collection. In addition, Oragene·Dx device formats are made from the same physical and chemical materials. Oragene·Dx formats differ in the amount of DNA stabilizing liquid in the tube and in the difference in the amount of saliva to be collected. The ratio of final sample to stabilizing liquid volume remains the same.

Saliva collection can take place at home, in a laboratory setting, physician's office, or in the field by untrained (naïve) or professional users. Saliva samples are collected into the device directly by spitting or by using the provided sponges. 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). Oragene·Dx Samples can be immediately processed, transported or stored for future use. Samples can be shipped at ambient temperature to the laboratory for processing.

Oragene·Dx device pre-collection shelf life is 24 months at room temperature from the date of manufacture. Post collection, Oragene·Dx samples are stable at room temperature for up to 12 months. Oragene·Dx device performance and sample integrity are maintained during typical ambient transport and storage conditions.

SUBSTANTIAL EQUIVALENCE INFORMATION

The following table outlines the similarities and differences between predicate and subject devices.

Principle, Materials and Technology	**Predicate devices** **Oragene·Dx: OGD-500, OGD-575, OYD-500, OXD-500 (k110701)**	**Subject devices** **Oragene·Dx: OGD-510, OGD-600, OGD-610, OGD-675**	**Similar**	**Different**
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	Same as predicate	X	

Principle, Materials and Technology	Predicate devices Oragene·Dx: OGD-500, OGD-575, OYD-500, OXD-500 (k110701)	Subject devices Oragene·Dx: OGD-510, OGD-600, OGD-610, OGD-675	Similar	Different
	and can be transported and/or stored long term at ambient conditions.			
Special conditions for use	Prescription	Same as predicate	X	
Analyte	Human DNA	Same as predicate	X	
Device physical design	Consists of a collection tube, a DNA stabilizing liquid and optional sponges for assisted collection.	Same as predicate	X	
Sample collection	Non-invasive collection of biological samples delivered into a non-sterile plastic collection tube	Same as predicate	X	
Instructions for use	Multiple languages	English only (except OGD-510)		X
Formats	Multiple	Same as predicate	X	
Tube material	Plastic	Same as predicate	X	
Sample source	Human saliva	Same as predicate	X	
Additive	Nucleic acid stabilization solution	Same as predicate	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 24 months Post-collection Oragene·Dx samples can be stored at room temperature for up to 12 months (OGD-500, OGD-575, OYD-500) and 3 months for OXD-525	Same as predicate	X	

Principle, Materials and Technology	Predicate devices Oragene·Dx: OGD-500, OGD-575, OYD-500, OXD-500 (k110701)	Subject devices Oragene·Dx: OGD-510, OGD-600, OGD-610, OGD-675	Similar	Different
Performance	Performance has been established with the eSensor® Warfarin Sensitivity Saliva Test	Same as predicate	X	

The similarities in intended use, materials, technological characteristics show that Oragene·Dx devices OGD-510, OGD-600, OGD-610, OGD-675 are *substantially equivalent* to Oragene·Dx devices (k110701). The difference tabulated above does not affect the safety and performance of the device. Oragene·Dx device performance has been validated using GenMark Diagnostics' FDA cleared eSensor Warfarin Sensitivity Saliva Test (k110786).

PERFORMANCE CHARACTERISTICS

REPRODUCIBILITY/PRECISION

The reproducibility of the Oragene·Dx devices has been demonstrated; **see section 18.4 of k110701.** Two reproducibility studies were performed and evaluated device reproducibility using prepared sample panels and the reproducibility of sample collection, processing and testing procedures. Overall, all samples tested met study acceptance criteria.

SHELF LIFE AND STABILITY

Pre-collection shelf-life

Shelf-life stability testing of the Oragene·Dx device has been demonstrated; **see Section 18.3 of k110701.** Oragene·Dx formats OGD-510, OGD-600, OGD-610 and OGD-675 are comprised of the same physical and chemical components as the FDA cleared Oragene·Dx formats; therefore, studies in k110701 support the following shelf-life performance claims:

- 24 months at room temperature
- 12 months at -20±5°C and 6±4°C

Post-collection sample stability

Post-collection sample stability of the Oragene·Dx devices has been demonstrated; see **Section 18.3 of k110701**. The Oragene·Dx formats OGD-510, OGD-600, OGD-610 and OGD-675 are comprised of the same physical and chemical components as the FDA cleared Oragene·Dx formats; therefore, studies in k110701 support the following sample stability performance claims:

- 12 months at room temperature, -20±5°C or 6±4°C
- 3 months at 50±5°C

DETECTION LIMIT

Sample Volume Tolerance

The effect of overfilling or underfilling the Oragene·Dx device has been demonstrated**; see section 18.2 of k110701**. Oragene·Dx formats OGD-510, OGD-600, OGD-610 and OGD-675 are comprised of the same physical and chemical components as the FDA cleared Oragene·Dx formats. As demonstrated, underfilling the Oragene·Dx device (OGD-500) by 25% or 50% of target volume, or overfilling by 50% of target volume did not impact performance. Collected samples ranged from as low as 0.58mL saliva to as much as 3.64 mL saliva. As expected the DNA yield was dependent on collected volume, but downstream performance was not affected by over or under spitting.

INTERFERING SUBSTANCES

The effect of endogenous and exogenous interfering substances has been demonstrated; **see Section 18.6 of K110701**. The Oragene·Dx formats OGD-510, OGD-600, OGD-610 and OGD-675 are comprised of the same physical and chemical components as the FDA cleared Oragene·Dx formats. In summary, in accordance with the donor collection instructions for use that specify no eating, drinking, smoking , or chewing gum 30 minutes prior to saliva collection this study demonstrates that there was no impact on performance from the introduction of either endogenous substances or exogenous substances into Oragene·Dx saliva samples. All samples tested had 100% agreement between eSensor® Warfarin Sensitivity Test genotyping and bidirectional sequencing.

COMPARISON STUDIES

Matrix comparison was evaluated in **k110701; see Section 18.5.** Method comparison studies were previously completed with the eSensor Warfarin Sensitivity Saliva Test; **see K110786**. The Oragene·Dx formats OGD-510, OGD-600, OGD-610 and OGD-675 are comprised of the same physical and chemical components as the FDA cleared Oragene·Dx formats, therefore these comparison studies are applicable.

A new study was conducted to evaluate the analytical performance of OGD-510 (DNA concentration, yield, A260/A280 ratio and agreement between genotyping on the eSensor Warfarin Sensitivity Saliva Test and bidirectional sequencing), and performance was compared to that of OGD-500. This study is also applicable to OGD-610 as it is an equivalent format to OGD-510. Overall, both OGD-510 and OGD-500 samples met acceptance criteria for DNA concentration, total DNA yield, A260/A280 ratio and performance on the eSensor Warfarin Sensitivity Saliva Test. There was no significant difference in any performance parameters (with the expected exception of total sample DNA yield) between the two formats.

CONCLUSION

The submitted information in this premarket notification is complete and supports the safety and effectiveness of the Oragene·Dx OGD-510, OGD-600, OGD-610 and OGD-675 formats and substantial equivalence to the predicate devices (Oragene·Dx K110701). As established in k110701 and in this submission, the difference in the formats of the subject Oragene·Dx devices conferred no differences in the performance of the stabilized and/or purified DNA.