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

February 19, 2015

DNA GENOTEK, INC.
DAN FULLERTON
VICE PRESIDENT OPERATIONS, QUALITY AND REGULATORY
2 BEAVERBROOK ROAD
OTTAWA K2K 1L1 CANADA

Re: K141410
Trade/Device Name: Oragene® Dx OGD-500.001
Regulation Number: 21 CFR 862.1675
Regulation Name: Blood specimen collection device
Regulatory Class: II
Product Code: OYJ
Dated: January 20, 2015
Received: January 21, 2015

Dear Mr. Dan 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,

Katherine Serrano -A

For: 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)*
k141410

Device Name
Oragene•Dx OGD-500.001

Indications for Use *(Describe)*
Oragene•Dx OGD-500.001 is intended for use in the non-invasive collection of saliva samples. DNA from the saliva sample is isolated, stabilized, and suitable for over-the-counter use with FDA cleared, approved, or legally marketed exempt DNA carrier screening genotyping tests. Saliva samples collected using Oragene•Dx OGD-500.001 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.

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:	16 January 2015
Submitter:	DNA Genotek Inc. 2 Beaverbrook Road, Ottawa, Ontario K2K 1L1 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-500.001
Common names	Kit for collection of human DNA, Saliva kit, Sample collection kit for use in over-the-counter genetic testing
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 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 OGD-500.001 is intended for use in the non-invasive collection of saliva samples. DNA from the saliva sample is isolated, stabilized, and suitable for over-the-counter use with FDA cleared, approved, or legally marketed exempt DNA carrier screening genotyping tests. Saliva samples collected using Oragene•Dx OGD-500.001 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

Intended for adults of reproductive age.

DEVICE DESCRIPTION

Oragene·Dx family of collection devices offers reliable collection, stabilization, transportation and long-term ambient temperature storage of human DNA from saliva. Oragene·Dx OGD-500.001 is a non-invasive alternative for collecting high quality and quantity DNA and is suitable for use in over-the-counter molecular genotyping applications. Oragene·Dx OGD-500.001 consists of a collection tube with a funnel lid attached (containing a stabilizing liquid). Saliva is delivered directly by spitting into the collection tube. Saliva collection can take place at home, in a laboratory setting, physician's office, 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. 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 (DNA). 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 samples are stable at room temperature for up to 12 months. Device and sample integrity are preserved during typical ambient transport and storage conditions.

SUBSTANTIAL EQUIVALENCE INFORMATION

The following table outlines the similarities and differences between Oragene·Dx OGD-500 (predicate) and Oragene·Dx OGD-500.001 (proposed device).

Table 1. Comparison between Predicate and Proposed device

Principle, Materials and Technology	Oragene·Dx OGD-500 (predicate – k110701)	Oragene·Dx OGD-500.001 (proposed device)	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 and can be transported and/or stored long term at ambient conditions.	Oragene®•Dx OGD-500.001 is intended for use in the non-invasive collection of saliva samples. DNA from the saliva sample is isolated, stabilized, and suitable for over-the-counter use with FDA cleared, approved, or legally marketed exempt DNA carrier screening genotyping tests. Saliva samples collected using Oragene•Dx OGD-500.001 are stabilized and can be transported and/or stored long term at ambient conditions.	X	
Special conditions for use	Prescription	Over the counter		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	
Tube material	Plastic	Plastic	X	
Sample source	Human saliva	Human saliva	X	
Additive	Nucleic acid stabilization solution	Nucleic acid stabilization solution	X	

Principle, Materials and Technology	Oragene·Dx OGD-500 (predicate – k110701)	Oragene·Dx OGD-500.001 (proposed device)	Similar	Different
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	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	X	
Performance	Performance has been established with the eSensor® Warfarin Sensitivity Saliva Test	Performance has been established with the 23andMe Personal Genome Service (PGS) Carrier Screening Test		X

The similarities in intended use, materials, and technological characteristics show that Oragene·Dx OGD-500.001 (k141410) is *substantially equivalent* to Oragene·Dx OGD-500 (k110701). The differences tabulated above do not affect the safety and performance of Oragene·Dx OGD-500.001. Oragene·Dx OGD-500 performance has been validated using GenMark Diagnostics' FDA cleared eSensor Warfarin Sensitivity Saliva Test. Oragene·Dx OGD-500.001 performance has been validated with the 23andMe PGS Carrier Screening Test.

PERFORMANCE CHARACTERISTICS

Reproducibility/Precision

Reproducibility of the Oragene·Dx OGD-500.001 collection device was validated when used with the 23andMe PGS Carrier Screening Test. Reproducibility was demonstrated across multiple operators, days and reagent lots (**see PGS Carrier Screening Test co-submission DEN140044**).

Stability

Pre-collection shelf-life

Shelf-life stability testing of the Oragene·Dx device has been demonstrated (**see k110701**).

The Oragene·Dx OGD-500.001 format is comprised of the same physical and chemical components as the FDA cleared Oragene·Dx OGD-500 format; therefore, studies in k110701 support the following shelf-life performance claims for OGD-500.001:

- 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 device (OGD-500) has been demonstrated in studies evaluating DNA yield, DNA concentration, A260/A280 ratio and microbial content (**see k110701**). The Oragene·Dx OGD-500.001 format is comprised of the same physical and chemical components as the FDA cleared Oragene·Dx OGD-500 format; therefore, studies in k110701 support the following sample stability performance claims for OGD-500.001:

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

Sample Volume Tolerance and Limit of Detection

The effect of overfilling or underfilling the Oragene·Dx device has been evaluated **(see k110701)**. Oragene·Dx OGD-500.001 format is comprised of the same physical and chemical components as the FDA cleared Oragene·Dx OGD-500 format. 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.

These results were further validated in a Consumer User Study where sample volume was measured in samples submitted from naive users in the over-the-counter setting of the 23andMe PGS Carrier Screening Test. Collected samples had a mean total sample volume (saliva + stabilizing solution) of 4.25 ± 0.56 mL (equivalent to mean of 2.25 mL saliva). 97.7% of samples contained the acceptable range of 2.58 to 5.64 mL total sample.

The 23andMe PGS Carrier Screening Test also requires a minimum DNA concentration. To ensure this concentration is met, the DNA concentration of every sample submitted for testing is measured. If the

extracted DNA concentration is below the minimum DNA concentration, re-extraction is attempted. If re-extraction is unsuccessful, the customer is contacted to submit a new saliva sample. 98.3% of samples in the study contained the minimum amount of DNA required for testing.

Interfering Substances

Endogenous Substances

The effect of potentially interfering endogenous substances on performance of saliva samples collected with the Oragene·Dx OGD-500.001 device on the 23andMe PGS Carrier Screening Test was evaluated (**see PGS co-submission DEN140044**). Saliva samples were collected from 10 individuals. These saliva samples were sent to the contracted laboratory for DNA extraction and genotyping. At the contracted laboratory, the following substances were spiked separately into an aliquot of each saliva sample before DNA extraction: salivary α-amylase, hemoglobin, immunoglobulin A, and a combination of α-amylase, immunoglobulin, and human serum albumin (total protein). An additional saliva sample aliquot was not spiked and served as the control. For each individual, genotypes of the samples containing each endogenous substance were compared with the genotype of the original unadulterated sample (considered control) to determine percent concordance.

This endogenous interference study yielded 100% concordant genotype calls for all samples and all endogenous substance conditions. The results of this study indicate that the presence of endogenous substances in human saliva does not affect the ability of the 23andMe PGS Carrier Screening Test to correctly assign genotypes to saliva samples.

Exogenous Substances

The effect of potentially interfering exogenous substances on the performance of saliva samples collected with the Oragene·Dx OGD-500.001 device on the PGS Carrier Screening Test has been evaluated (**see PGS co-submission DEN140044**). Saliva samples were collected from 5 individuals at 3 time points – before consuming an exogenous substance (baseline), immediately (0 minutes) after, and 30 minutes after – and sent to the contracted laboratory for DNA extraction and genotyping. For each individual, genotypes of the 0 and 30 minute samples were compared with genotypes of the baseline sample (considered control) to determine percent concordance. The following exogenous interference conditions were tested separately: eating food containing beef, eating food other than beef, drinking, chewing gum, and using mouthwash. Smoking was tested following the same methodology in a separate study.

This interference study yielded 100% concordant genotype calls for all samples collected immediately after and 30 minutes after consuming an exogenous substance or smoking. These data are consistent with the package insert instructions, which require the consumer to take nothing by mouth for 30 minutes prior to saliva collection.

Consumer User Study

Performance of the Oragene·Dx OGD-500.001 device when used in the over-the-counter setting of the 23andMe PGS Carrier Screening Test was evaluated. New 23andMe customers who registered their kit within consecutive 24-hour periods were invited to participate in the study survey via email. Samples from customers who completed the survey were shipped to the testing laboratory. Upon receipt at the testing laboratory, each study sample was assessed for compliance to collection instructions and sample volume, DNA concentration, and DNA purity (A260/A280 ratio) was assessed. User comprehension of test instructions, including comprehension of sample collection instructions was also assessed.

A total of 302 individuals completed the user comprehension survey and provided a saliva sample for analysis. The majority of participants (96.3%) were naïve to the device and saliva collection process. Of the 302 samples evaluated, 98.3% contained the minimum amount of DNA required for testing, demonstrating that customers were able to follow sample collection instructions to obtain adequate sample for testing. See PGS co-submission DEN140044 for additional user study information.

A Flesch-Kincaid reading analysis was performed on the collection device labeling and a reading grade level of 7.1 was obtained.

CONCLUSION

The submitted information in this premarket notification is complete and supports the safety and effectiveness of the Oragene·Dx OGD-500.001 for over-the-counter use.