October 28, 2020

Austin Udocor
Senior Manager, Regulatory Affairs
DNA Genotek Inc.
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Ottawa, CAN K2V 1C2 Ontario

Devices:	OMNIgene·ORAL OM-505 and OME-505 (OMNIgene·ORAL) saliva collection devices
Company:	DNA Genotek Inc.
Indication:	The OMNIgene·ORAL OM-505 and OME-505 (OMNIgene·ORAL) saliva collection devices are intended for use by individuals to collect, stabilize, and maintain during transport, saliva specimens suspected of containing SARS-CoV-2 ribonucleic acid (RNA).

Dear Mr. Udocor:

On October 14, 2020, based on your[1] request, the Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for emergency use of your product,[2] pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3).

On October 17, 2020, you requested to amend your EUA to update the kit components. Based on this request, and having concluded that revising the October 14, 2020, EUA is appropriate to protect the public health or safety under section 564(g)(2)(C) of the Act (21 U.S.C. § 360bbb-3(g)(2)(C)), FDA is reissuing the October 14, 2020, letter in its entirety with the revisions incorporated.[3] Pursuant to section 564 of the Act and the Scope of Authorization (Section II) and Conditions of Authorization (Section IV) of this reissued letter, your product is now authorized for use consistent with the indication described above.

On February 4, 2020, pursuant to Section 564(b)(1)(C) of the Act, the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency that has a significant potential to affect national security or the health and security of

[1] For ease of reference, this letter will use the term "you" and related terms to refer to DNA Genotek Inc.
[2] For ease of reference, this letter will use the term "your product" to refer to the OMNIgene·ORAL OM-505 and OME-505 (OMNIgene·ORAL) saliva collection devices used for the indication identified above.
[3] The revisions to the October 14, 2020, letter and labeling were to update the list of kit components and fix any typographical-type errors..

United States citizens living abroad, and that involves the virus that causes COVID-19.[4] Pursuant to Section 564 of the Act, and on the basis of such determination, the Secretary of HHS then declared on March 24, 2020, that circumstances exist justifying the authorization of emergency use of medical devices during the COVID-19 outbreak, subject to the terms of any authorization issued under Section 564(a) of the Act.[5]

There are no FDA-approved or -cleared devices for collection of viral RNA in saliva for diagnostic testing. FDA considered the totality of scientific information available in authorizing the emergency use of your product for the indication above. A summary of the performance information FDA relied upon is contained in the EUA Summary (identified below).

Having concluded that the criteria for issuance of this authorization under Section 564(c) of the Act are met, I am authorizing the emergency use of your product, described in the Scope of Authorization of this letter (Section II), subject to the terms of this authorization.

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of your product meets the criteria for issuance of an authorization under Section 564(c) of the Act, because I have concluded that:

1. The SARS-CoV-2 can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus;

2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that your product may be effective in diagnosing COVID-19 by serving as an appropriate means to collect, stabilize, and maintain during transport, saliva specimens suspected of containing SARS-CoV-2 RNA, and that the known and potential benefits of your product when used for such use, outweigh the known and potential risks of your product; and

3. There is no adequate, approved, and available alternative to the emergency use of your product.[6]

II. Scope of Authorization

I have concluded, pursuant to Section 564(d)(1) of the Act, that the scope of this authorization is limited to the indication above.

Authorized Product Details

[4] U.S. Department of Health and Human Services, *Determination of a Public Health Emergency and Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3*. 85 FR 7316 (February 7, 2020).
[5] U.S. Department of Health and Human Services, *Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3*. 85 FR 17335 (March 27, 2020)
[6] No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the Act.

Your product is intended for use by individuals to collect, stabilize, and maintain during transport, saliva specimens suspected of containing SARS-CoV-2 ribonucleic acid (RNA). The devices may be used for specimen self-collection by a layperson (e.g., supervised by a healthcare worker in a healthcare setting) or for specimen collection by a healthcare worker.[7]

The OMNIgene·ORAL saliva collection devices both include the following materials or other authorized materials: clamshell primary packaging, Instructions for Use (IFU), collection tube and funnel, membrane seal material on collection tube funnel, stabilizing liquid, Stabilizing Liquid Component 2, collection tube wrap around label, collection tube cap, (±) collection tube cap insert.

Authorized labeling includes the following documents: EUA Summary, and OMNIgene·ORAL Saliva Collection Devices patient IFU: "OMNIgene·ORAL OM-505 User Instructions," and "OMNIgene·ORAL OME-505 User Instructions" (available at https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas).

The above described products, with the authorized labeling provided as set forth in the Conditions of Authorization (Section IV) below, are authorized to be distributed and used as set forth in this letter and pursuant to the conditions in this EUA, despite the fact that they do not meet certain requirements otherwise required by applicable federal law.

I have concluded, pursuant to Section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of your product, when used consistent with the Scope of Authorization of this letter (Section II), outweigh the known and potential risks of your product.

I have concluded, pursuant to Section 564(d)(3) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that your product may be effective in diagnosing COVID-19 by serving as an appropriate means to collect, stabilize, and maintain during transport, saliva specimens suspected of containing SARS-CoV-2 RNA, when used consistent with the Scope of Authorization of this letter (Section II), pursuant to Section 564(c)(2)(A) of the Act.

FDA has reviewed the scientific information available to FDA, including the information supporting the conclusions described in Section I above, and concludes that your product (as described in the Scope of Authorization of this letter (Section II)) meets the criteria set forth in Section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of your product under this EUA must be consistent with, and may not exceed, the terms of this letter, including the Scope of Authorization (Section II) and the Conditions of Authorization (Section IV). Subject to the terms of this EUA and under the circumstances set forth in the Secretary of HHS's determination under Section 564(b)(1)(C) of the Act described above and the Secretary of HHS's corresponding declaration under Section 564(b)(1) of the Act, your product is authorized for the indication above.

[7] While this EUA does not authorize your product as standalone self-collection devices, the OMNIgene·ORAL OM-505 and OME-505 may be included as a component of an authorized or cleared self-collection kit (e.g., as part of a kit that is authorized under its own EUA for use by an individual to collect saliva specimens at home).

III. Waiver of Certain Requirements

I am waiving the following requirements for your product during the duration of this EUA:

- Current good manufacturing practice requirements, including the quality system requirements under 21 CFR Part 820 with respect to the design, manufacture, packaging, labeling, storage, and distribution of your product, but excluding Subpart H (Acceptance Activities, 21 CFR 820.80 and 21 CFR 820.86), Subpart I (Nonconforming Product, 21 CFR 820.90), and Subpart O (Statistical Techniques, 21 CFR 820.250).

IV. Conditions of Authorization

Pursuant to Section 564(e) of the Act, I am establishing the following conditions on this authorization:

DNA Genotek Inc. (You) and Authorized Distributor(s)[8]

A. Your product must comply with the following labeling requirements under FDA regulations: the intended use statement (21 CFR 809.10(a)(2), (b)(2)); adequate directions for use (21 U.S.C. 352(f)), (21 CFR 809.10(b)(5), (7), and (8)); appropriate limitations on the use of the device including information required under 21 CFR 809.10(a)(4); and any available information regarding performance of the device, including requirements under 21 CFR 809.10(b)(12).

B. You and authorized distributor(s) will make available on your website(s), the authorized labeling and ship the applicable patient IFU ("OMNIgene·ORAL OM-505 User Instructions," or "OMNIgene·ORAL OME-505 User Instructions") with each saliva collection device.

C. Through a process of inventory control, you and authorized distributor(s) will maintain records of the numbers and locations to which your product is distributed.

D. You and authorized distributor(s) will maintain customer complaint files on record. You will report to FDA any significant complaints about usability or deviations from the established performance characteristics of the product of which you become aware.

E. You and authorized distributor(s) are authorized to make available additional information relating to the emergency use of your product that is consistent with, and does not exceed, the terms of this letter of authorization.

F. You and authorized distributors using your product will ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records

[8] "Authorized Distributor(s)" are identified by you, DNA Genotek Inc, in your EUA submission as an entity allowed to distribute your product.

will be made available to FDA for inspection upon request.

DNA Genotek Inc. (You)

G. You will notify FDA of any authorized distributor(s) of your product, including the name, address, and phone number of any authorized distributor(s).

H. You will provide authorized distributor(s) with a copy of this EUA and communicate any subsequent revisions that might be made to this EUA and its authorized labeling.

I. You may request changes to this EUA for your product, including to the Scope of Authorization (Section II in this letter) or to the authorized labeling, including requests to make available additional authorized labeling specific to an authorized distributor. Such additional labeling may use another name for your product but otherwise must be consistent with the authorized labeling, and not exceed the terms of authorization of this letter. Any request for changes to this EUA should be submitted to the Division of Microbiology (DMD)/Office of Health Technology 7 (OHT7)-Office of In Vitro Diagnostics and Radiological Health (OIR)/Office of Product Evaluation and Quality (OPEQ)/Center for Devices and Radiological Health (CDRH) and require appropriate authorization from FDA prior to implementation.

J. You will comply with the following requirements pursuant to FDA regulations: Subpart H (Acceptance Activities, 21 CFR 820.80 and 21 CFR 820.86), Subpart I (Nonconforming Product, 21 CFR 820.90), and Subpart O (Statistical Techniques, 21 CFR 820.250).

K. You must have lot release procedures and the lot release procedures, including the study design and statistical power, must ensure that the devices released for distribution have the clinical and analytical performance claimed in the authorized labeling.

L. If requested by FDA, you must submit lot release procedures to FDA, including sampling protocols, testing protocols, and acceptance criteria, that you use to release lots of your product for distribution in the U.S. If such lot release procedures are requested by FDA, you must provide it within 48 hours of the request.

M. You will track adverse events associated with your product and report to FDA pursuant to 21 CFR Part 803. Serious adverse events, especially unexpected biosafety concerns, should also immediately be reported to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUAReporting@fda.hhs.gov).

Conditions Related to Printed Materials, Advertising and Promotion

N. All descriptive printed matter, including advertising and promotional materials, relating to the use of your product shall be consistent with the authorized labeling, as well as the terms set forth in this EUA and the applicable requirements set forth in the Act and FDA regulations.

O. No descriptive printed matter, including advertising or promotional materials, relating to the use of your product may represent or suggest that this device is safe or effective for the detection of SARS-CoV-2.

P. All descriptive printed matter, including advertising and promotional materials, relating to the use of your product shall clearly and conspicuously state that:

- This sample collection device has not been FDA cleared or approved;
- This sample collection device has been authorized by FDA under an EUA;
- This sample collection device has been authorized only to collect, stabilize, and maintain during transport, saliva specimens suspected of containing SARS-CoV-2 ribonucleic acid (RNA), not for any other viruses or pathogens; and
- This sample collection device is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in medical devices during the COVID-19 outbreak under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

The emergency use of your product as described in this letter of authorization must comply with the conditions and all other terms of this authorization.

V. Duration of Authorization

This EUA will be effective until the declaration that circumstances exist justifying the authorization of the emergency use of medical devices during the COVID-19 outbreak is terminated under Section 564(b)(2) of the Act or the EUA is revoked under Section 564(g) of the Act.

Sincerely,

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RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

Enclosure