March 17, 2022

Gloria Lee, Ph.D.
Sr. Director Regulatory Affairs
Helix OpCo LLC (dba Helix)
101 S Ellsworth, Suite 350
San Mateo, CA 94401

Device:	Helix SARS-CoV-2 Test
EUA Number:	EUA210668
Company:	Helix OpCo LLC (dba Helix)
Indication:	This test is authorized for the qualitative detection of nucleic acid from SARS-CoV-2 in anterior nasal swab specimens that are self-collected without supervision using the Helix COVID-19 Self-Collection Kit by individuals 18 years or older who are suspected of COVID-19 by a healthcare provider. Emergency use of this test is limited to the authorized laboratories.
Authorized Laboratories:	Testing is limited to Helix laboratories located at 6925 Lusk Blvd., San Diego, CA 92121 and 9875 Towne Centre Dr., San Diego, CA 92121, which are certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a and meet requirements to perform high complexity tests.

Dear Dr. Lee:

This letter is in response to your[1] request that the Food and Drug Administration (FDA) issue 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 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 United States citizens living abroad, and that involves the virus that causes COVID-19. Pursuant to Section 564 of the Act, and on the basis of such determination, the Secretary of HHS then declared that circumstances exist justifying the authorization of emergency use of in

[1] For ease of reference, this letter will use the term "you" and related terms to refer to Helix OpCo LLC (dba Helix).
[2] For ease of reference, this letter will use the term "your product" to refer to the Helix SARS-CoV-2 Test used for the indication identified above.

vitro diagnostics for detection and/or diagnosis of the virus that causes COVID-19 subject to the terms of any authorization issued under Section 564(a) of the Act.[3]

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, and that the known and potential benefits of your product when used for diagnosing COVID-19, 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.[4]

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
Your product is a qualitative test for the detection of nucleic acid from SARS-CoV-2 anterior nasal swab specimens that are self-collected without supervision using the Helix COVID-19 Self-Collection Kit by individuals 18 years or older who are suspected of COVID-19 by a healthcare provider. Testing is limited to Helix laboratories located at 6925 Lusk Blvd., San Diego, CA 92121 and 9875 Towne Centre Dr., San Diego, CA 92121, which are certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a and meet requirements to perform high complexity tests.

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[3] 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).
[4] No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the Act.

The SARS-CoV-2 nucleic acid is generally detectable in anterior nasal swab specimens during the acute phase of infection. Positive results are indicative of the presence of SARS-CoV-2 nucleic acid; clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information.

The Helix COVID-19 Self-Collection Kit provides specimen collection and storage materials as well as materials for user drop off at a designated drop-off box for shipment to the testing laboratory, as described in the "Helix COVID-19 Self-Collection Kit Instructions (Unsupervised)".

To use your product, SARS-CoV-2 nucleic acid is first extracted, isolated and purified from anterior nasal swab specimens. The purified nucleic acid is then reverse transcribed into cDNA followed by PCR amplification and detection using an authorized real-time (RT) PCR instrument described in the authorized labeling (described below).

Your product uses all commercially sourced materials or other authorized materials and authorized ancillary reagents commonly used in clinical laboratories, as described in the authorized labeling (described below).

Your product requires use of control materials or other authorized control materials (as may be requested under Condition P below) that are described in the authorized labeling (described below). All controls must generate expected results in order for a test to be considered valid, as outlined in the authorized labeling (described below).

The above described product is authorized to be accompanied with laboratory procedures (described below), the EUA Summary (available at https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas), and the following fact sheets pertaining to the emergency use, which are required to be made available to healthcare providers and patients:

- Fact Sheet for Healthcare Providers: Helix - Helix SARS-CoV-2 Test
- Fact Sheet for Patients: Helix - Helix SARS-CoV-2 Test

The above described product, when accompanied by the laboratory procedures ("Automated – Make COV2 Plating and Heating of SSP Samples for Helix SARS-CoV-2 Test" SOP, "Automated – Make RT-qPCR Setup and Loading of Reaction Plate for Helix SARS-CoV-2 Test" SOP, "Specimen Decapping and Automated - Make SSP Plating for the Helix SARS-CoV-2 Test" SOP, "Helix SARS-CoV-2 Test, Specimen Receipt, Quality Control, and Processing" SOP, and "Data Analysis and Interpretation for the Helix SARS-CoV-2 Test" SOP), the EUA Summary (identified above), and the two Fact Sheets, is authorized to be distributed to and used by the two authorized laboratories under this EUA, despite the fact that it does not meet certain requirements otherwise required by applicable federal law.

The Helix COVID-19 Self-Collection Kit with the "Helix COVID-19 Self-Collection Kit Instructions (Unsupervised)" is authorized to be distributed and used as part of the above described product as set forth in this EUA.

"Authorized labeling" refers to the laboratory procedures, EUA Summary, "Helix COVID-19 Self-Collection Kit Instructions (Unsupervised)", and the two fact sheets.

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, 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.

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.

IV. Conditions of Authorization

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

Helix (You) and Authorized Distributor(s)[5]

[5] "Authorized Distributor(s)" are identified by you, Helix, in your EUA submission as an entity allowed to distribute the Helix COVID-19 Self-Collection Kit.

A. Your product must comply with the following labeling requirements pursuant to 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) must make available on your website(s), if applicable, the Fact Sheet for Healthcare Providers and Fact Sheet for Patients.

C. You and authorized distributor(s) must make available all instructions related to the self-collection of anterior nasal swab specimens using the Helix COVID-19 Self-Collection Kit as a hardy copy in the kit, electronically to the registrant after successful registration (e.g., via email or text) and on a video monitor at the collection station.

D. Through a process of inventory control, you and authorized distributor(s) must maintain records of the numbers (of kits and lot numbers) and locations to which the Helix COVID-19 Self-Collection Kit is distributed.

E. You and authorized distributor(s) must maintain customer complaint files concerning the Helix COVID-19 Self-Collection Kit on record. You must report to FDA any significant complaints about usability or deviations from the established performance characteristics of the product of which you become aware.

F. 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.

G. You and authorized distributor(s) must ensure that any records associated with this EUA, including test usage, are maintained until otherwise notified by FDA. Such records must be made available to FDA for inspection upon request.

Helix (You)

H. You must notify FDA of any authorized distributor(s) of the Helix COVID-19 Self-Collection Kit, including the name, address, and phone number of any authorized distributor(s).

I. You must provide authorized distributor(s) with a copy of this EUA and communicate to authorized distributor(s) any subsequent amendments that might be made to this EUA and its authorized accompanying materials (e.g., Fact Sheets).

J. You must inform relevant public health authorities of this EUA, including the terms and conditions herein, and any updates made to your product and authorized labeling.

K. You must notify the relevant public health authorities of your intent to run your product prior to initiating testing.

L. You must have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.

M. You must include with test result reports, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.

N. You must use your product as outlined in the authorized labeling. Deviations from the authorized procedures, including the authorized instruments, authorized extraction methods, authorized clinical specimen types, authorized control materials, authorized other ancillary reagents and authorized materials required to use your product are not permitted.

O. When testing specimens self-collected using the Helix COVID-19 Self-Collection Kit, you must have in place a suitable specimen receipt and accessioning SOP.

P. 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 the 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.

Q. You must evaluate the analytical limit of detection and assess traceability of your product with any FDA-recommended reference material(s), if requested by FDA.[6] After submission to and concurrence with the data by FDA, FDA will update the EUA Summary to reflect the additional testing.

R. You must have a process in place to track adverse events, including any occurrence of false results with your product, including with the Helix COVID-19 Self-Collection Kit and report any such events to FDA pursuant to 21 CFR Part 803. Serious adverse events, especially unexpected biosafety concerns, should immediately be reported to DMD/OHT7- OIR/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov).

S. You must collect information on the performance of your product and report to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov) any

[6] Traceability refers to tracing analytical sensitivity/reactivity back to an FDA-recommended reference material. FDA may request, for example, that you perform this study in the event that we receive reports of adverse events concerning your product.

suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of your product of which you become aware.

T. All laboratory personnel using your product must be appropriately trained in RT-PCR techniques and use appropriate laboratory and personal protective equipment when handling this kit and use your product in accordance with the authorized labeling.

U. You must collect information on the performance of your product and report to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUAReporting@fda.hhs.gov) any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of your product of which you become aware.

V. You must submit to FDA a summary report within 30 calendar days of product launch summarizing the results of any testing performed using anterior nasal swab specimens collected with the Helix COVID-19 Self-Collection Kit during that timeframe, including how many kits were requested and registered via any online patient portal, how many samples were bulk shipped for testing, how many specimens were processed, how many specimens were rejected during accessioning and the reasons for rejection, the SARS-CoV-2 positivity rate, the invalid rate (due to RNase P failure), as well as the number of calls reported to Helix's customer service and authorized distributor staff (e.g., store staff) along with the nature of the calls.

W. You must further evaluate the stability of SARS-CoV-2 RNA in specimens collected using the Helix COVID-19 Self-Collection Kit in an FDA agreed upon post authorization study within 2 months of the date of this letter (unless otherwise agreed to with DMD/OHT7-OIR/OPEQ/CDRH). After submitting the data to FDA and obtaining FDA concurrence regarding the conclusions of the study, you must update your authorized labeling to reflect the additional testing. Such labeling updates will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

X. You must evaluate the stability of your collection kit components over their proposed shelf life, including exposure to conditions that may be experienced during storage in a locker prior to patient retrieval in an FDA agreed upon post authorization reagent stability study. Within 2 months of the date of this letter (unless otherwise agreed to with DMD/OHT7-OIR/OPEQ/CDRH) you must submit a plan to conduct a reagent stability study with your kit's final packaging to support your expiration dating. You will initiate the study after obtaining FDA concurrence with the plan and update your labeling at the conclusion of the study to reflect the additional testing, as appropriate. Such labeling updates will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

Y. You must submit a detailed explanation of your software development and validation procedures as agreed. You must address any gaps that are identified and if necessary,

implement corrective actions within 6 months of the date of this letter (unless otherwise agreed to with DMD/OHT7-OIR/OPEQ/CDRH).

Z. You must further evaluate the effect of potential cross-reaction with common respiratory pathogens and commensal species on the performance of your product in an FDA agreed upon post authorization analytical study within 2 months of the date of this letter (unless otherwise agreed to with DMD/OHT7-OIR/OPEQ/CDRH). After submitting the data to FDA and obtaining FDA concurrence regarding the conclusions of the study, you will update your labeling to reflect the additional testing. Such labeling updates will be made in consultation with, and require concurrence of, DMD/OHT7- OIR/OPEQ/CDRH.

AA. You must evaluate the effect on the performance of your product of on-panel (i.e., influenza A and influenza B) and off-panel analytes when present at high concentrations via wet testing in an FDA agreed upon post authorization analytical study within 2 months of the date of this letter (unless otherwise agreed to with DMD/OHT7-OIR/OPEQ/CDRH). After submitting the data to FDA and obtaining FDA concurrence regarding the conclusions of the study, you will update your labeling to reflect the additional testing. Such labeling updates will be made in consultation with, and require concurrence of, DMD/OHT7- OIR/OPEQ/CDRH.

BB. You must evaluate the effect of endogenous and exogenous substances on the performance of your product in an FDA agreed upon post authorization analytical study within 2 months of the date of this letter (unless otherwise agreed to with DMD/OHT7-OIR/OPEQ/CDRH). After submitting the data to FDA and obtaining FDA concurrence regarding the conclusions of the study, you will update your labeling to reflect the additional testing. Such labeling updates will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

CC. You must evaluate the impact of SARS-CoV-2 viral mutations on your product's performance. Such evaluations must occur on an ongoing basis and must include any additional data analysis that is requested by FDA in response to any performance concerns you or FDA identify during routine evaluation. Additionally, if requested by FDA, you must submit records of these evaluations for FDA review within 48 hours of the request. If your evaluation identifies viral mutations that affect the stated expected performance of your device, you must notify FDA immediately (via email: CDRH-EUA-Reporting@fda.hhs.gov).

DD. If requested by FDA, you must update your labeling within 7 calendar days to include any additional labeling risk mitigations identified by FDA regarding the impact of viral mutations on test performance. Such updates will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

Conditions Related to Printed Materials, Advertising and Promotion

EE. All descriptive printed matter, 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 meet the requirements set forth in section 502(a), (q)(1), and (r) of

the Act, as applicable, and FDA implementing regulations.

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

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

- This product has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an EUA for use by the authorized laboratory;
- This product has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens; and
- The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is 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 in vitro diagnostics for detection and/or diagnosis of COVID-19 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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Jacqueline A. O'Shaughnessy, Ph.D.
Acting Chief Scientist
Food and Drug Administration

Enclosure