March 19, 2021

Tiger Tech Solutions, Inc.
c/o Mr. Andrew Ittleman
Fuerst Ittleman David & Joseph
1 SE 3rd Ave, Suite 1800
Miami, FL 33131

Dear Mr. Ittleman:

This letter is in response to your request that the Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for emergency use of the Tiger Tech COVID Plus Monitor intended for use by trained personnel to help prevent exposure to and spread of SARS-CoV-2, the virus that causes coronavirus disease 2019 (COVID-19), by identifying certain biomarkers[1] in asymptomatic individuals over the age of 5, when performed following a temperature reading that does not meet the criteria for fever in settings where temperature check is being conducted in accordance with Centers for Disease Control and Prevention (CDC) and local institutional infection prevention and control guidelines.[2]

On February 4, 2020, pursuant to section 564(b)(1)(C) of the Federal Food, Drug, and Cosmetic Act (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.[3] 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 that section.[4]

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[1] The Tiger Tech COVID Plus Monitor identifies certain biomarkers that are indicative of SARS-COV-2 infection, as well as other hypercoagulable conditions (such as disseminated intravascular coagulation, sepsis, or cancer) or hyper-inflammatory states (such as severe allergic reactions).

[2] A temperature check is commonly performed to screen for SARS-CoV-2 infection. For example, it is considered by CDC to be an optional strategy for reducing the spread of COVID-19 in workplaces (https://www.cdc.gov/coronavirus/2019-ncov/community/guidance-business-response.html#anchor_1609683211941) and community locations (https://www.cdc.gov/coronavirus/2019-ncov/community/schools-childcare/symptom-screening.html). The Tiger Tech COVID Plus Monitor is authorized to be used only as a secondary screening device in settings where temperature check is being conducted for screening for potential SARS-CoV-2 infection risk.

[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] U.S. Department of Health and Human Services, *Declaration that Circumstances Exist Justifying Authorizations*

There are no adequate, FDA approved or cleared device alternatives available for preventing exposure to and spread of COVID-19 by identifying certain biomarkers in asymptomatic (including non-febrile) individuals over the age of 5. Two studies compared the Tiger Tech COVID Plus Monitor predictions against reverse transcription polymerase chain reaction (RT-PCR) diagnosis results in asymptomatic individuals, one in a hospital and another in a K-12 school setting. The hospital study, which was considered a validation study, included a total of 69 confirmed positive cases and 398 confirmed negative cases and yielded a point estimate of positive percent agreement (PPA) of 98.6% and negative percent agreement (NPA) of 94.5%. The school study, which was considered a confirmatory study, included a total of 7 confirmed positive cases and 412 confirmed negative cases and yielded a point estimate of PPA of 100% and NPA of 100%. Based on these two clinical performance studies and the totality of scientific evidence available, FDA has concluded that the Tiger Tech COVID Plus Monitor, when used by trained personnel, may be effective at preventing exposure to and spread of SARS-CoV-2 by identifying certain biomarkers in asymptomatic individuals over the age of 5, when performed following a temperature reading that does not meet the criteria for fever in settings where temperature check is being conducted in accordance with CDC and local institutional infection prevention and control guidelines.

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 the Tiger Tech COVID Plus Monitor, as described in the Scope of Authorization (Section II) and pursuant to the Conditions of Authorization (Section IV) of this letter.

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of the Tiger Tech COVID Plus Monitor, as described in the Scope of Authorization (Section II) of this letter, meets the criteria for issuance of an authorization under section 564(c) of the Act, because I have concluded that:

1. SARS-CoV-2, the virus that causes COVID-19, 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 the Tiger Tech COVID Plus Monitor, when used by trained personnel, may be effective at preventing exposure to and spread of SARS-CoV-2 by identifying certain biomarkers in asymptomatic individuals over the age of 5, when performed following a temperature reading that does not meet the criteria for fever in settings where temperature check is being conducted in accordance with CDC and local institutional infection prevention and control guidelines, and that the known and potential benefits of such product, when used as described in the Scope of Authorization of this letter (Section II), outweigh the known and potential risks; and,

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).

3. There is no adequate, approved, and available alternative to the emergency use of the Tiger Tech COVID Plus Monitor for such use.[5]

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 use of the Tiger Tech COVID Plus Monitor by trained personnel to help prevent exposure to and spread of SARS-CoV-2 by identifying certain biomarkers in asymptomatic individuals over the age of 5, when performed following a temperature reading that does not meet the criteria for fever in settings where temperature check is being conducted in accordance with CDC and local institutional infection prevention and control guidelines.[6]

The Authorized Tiger Tech COVID Plus Monitor

The Tiger Tech COVID Plus Monitor is an armband with two embedded photoplethysmography (PPG) sensors and a processor. During use, the armband is wrapped around the recipient's[7] bare left arm above the elbow. The PPG sensors acquire direct pulsatile biosignals over a period of 3-5 minutes from the outer left bicep. The processor interprets the signals obtained by the sensors. First, a series of morphological features ("biomarkers") are extracted from the pulsatile signals, which have been correlated with certain conditions, including the hypercoagulable state[8], that may be associated with SARS-CoV-2 infection. These features are fed into a probabilistic machine learning model that has been trained to make predictions on whether the individual is showing certain signals, such as hypercoagulation in blood. The model requires roughly two minutes of motionless (artifact-free) data to provide the screening result by display of a colored light:

- A green light indicates that the recipient is not demonstrating certain biomarkers of certain conditions, such as hypercoagulation in blood.
- A red light indicates that the recipient is demonstrating certain biomarkers of certain conditions, such as hypercoagulation in blood.
- A blue light indicates that the test is inconclusive due to indeterminate features. The authorized labeling provides instructions on how to respond to a blue light.

The Tiger Tech COVID Plus Monitor Package Insert/Instructions for Use (available at https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations) includes a decision tree to inform decisions on whether to deny or allow admittance of an individual based on which light is displayed by the authorized product and to instruct users[9] to direct the recipients accordingly per established CDC and local institutional

[5] No other criteria of issuance have been prescribed by regulation under section 564(c)(4) of the Act.
[6] See footnote 2.
[7] Recipient refers to an asymptomatic individual over the age of 5 who is being screened for certain biomarkers using the Tiger Tech COVID Plus Monitor.
[8] Abou-Ismail M. Y., A. Diamond, S. Kapoor, Y. Arafah, and L. Nayak, The hypercoagulable state in COVID-19: Incidence, pathophysiology, and management. Thromb Res 2020;194:101-115.
[9] User refers to a trained individual who performs screening for certain biomarkers using the Tiger Tech COVID Plus Monitor.

prevention and control guidelines for temperature check.

The Tiger Tech COVID Plus Monitor is comprised of the following components:

- Tiger Tech COVID Plus Monitor unit
- Wearable band
- 9V battery

The above described Tiger Tech COVID Plus Monitor is authorized to be accompanied with the device labeling, entitled "Tiger Tech COVID Plus Monitor Package Insert/Instructions for Use" (available at https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations), together with the following product-specific information pertaining to emergency use, which is required to be made available to the users and recipients, respectively:

- Fact Sheet for Users: Emergency Use of Tiger Tech COVID Plus Monitor During the COVID-19 Pandemic; and
- Fact Sheet for Recipients: Emergency Use of Tiger Tech COVID Plus Monitor During the COVID-19 Pandemic.

The above described product, when accompanied by the Package Insert/Instructions for Use (identified above) and the two Fact Sheets (referred to as "authorized labeling"), is authorized to be distributed under this EUA, despite the fact that it does not meet certain requirements otherwise required by 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 the Tiger Tech COVID Plus Monitor, when used as described in the Scope of Authorization of this letter (Section II), outweigh the known and potential risks of this 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 the authorized Tiger Tech COVID Plus Monitor, when used by trained personnel, may be effective at preventing exposure to and spread of SARS-CoV-2, when used consistently 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 the authorized Tiger Tech COVID Plus Monitor, 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 the Tiger Tech COVID Plus Monitor 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 and conditions 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, the Tiger Tech COVID Plus Monitor is authorized for emergency use, as described in the Scope of Authorization (Section II).

III. Waiver of Certain FDA Requirements

I am waiving the applicable good manufacturing practice requirements otherwise applicable to the manufacture, processing, packing, or holding of products subject to regulations under the Act, including the quality system requirements under 21 CFR Part 820, for the Tiger Tech COVID Plus Monitor during the duration of this EUA.

IV. Conditions of Authorization

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

Tiger Tech Solutions, Inc. ("Tiger Tech Solutions")

A. Tiger Tech Solutions must comply with the labeling requirements under 21 CFR Part 801 Subpart A (general labeling provisions), as well as those described in Section II of this letter, the Scope of Authorization. Compliance with unique device identification regulations (see Subpart B of 21 CFR Part 801) is not required under this EUA.

B. Tiger Tech Solutions must make the Tiger Tech COVID Plus Monitor available with the authorized labeling.

C. Tiger Tech Solutions may request changes to this EUA for the Tiger Tech COVID Plus Monitor, including changes to the authorized labeling. Any requests for changes to this EUA must be submitted to the Office of Health Technology 2 (OHT2)/Office of Product Evaluation and Quality (OPEQ)/Center for Devices and Radiological Health (CDRH). Such changes require appropriate authorization from FDA prior to implementation.[10]

D. Tiger Tech Solutions must have processes in place for developing, maintaining, and implementing medical device reporting (MDR) procedures, and must report to FDA adverse events of which they become aware in accordance with 21 CFR Part 803. Tiger Tech Solutions must establish a process to collect adverse event information from customers.

[10] The following types of revisions may be authorized without reissuing this letter: (1) non-substantive editorial corrections to this letter; (2) new types of authorized labeling, including new fact sheets; (3) new carton/container labels; (4) changes to manufacturing processes, including tests or other authorized components of manufacturing; (5) new conditions of authorization to require data collection or study; (6) new instruments, associated software, components or materials in the authorized product or modifications in the way that the device is used. All changes to the authorization require review and concurrence from OHT2/OPEQ/CDRH. For changes of the type listed in (5) or (6), review and concurrence also is required from the Office of Counterterrorism and Emerging Threats/Office of the Chief Scientist.

E. Tiger Tech Solutions must collect and submit to FDA additional clinical performance data for FDA review in accordance with the study plan agreed upon with OHT2/OPEQ/CDRH, to confirm the performance of the device in real-world settings. The study must provide the comparative outcomes of a total of 100 consecutive positive ("red light") cases and 1,000 consecutive negative ("green light") cases identified by the Tiger Tech COVID Plus Monitor that also received an FDA authorized COVID-19 RT-PCR test on the same day at participating sites. This information must be submitted to FDA according to the following schedule:

- 6-months post-initiation of distribution: a minimum of 30 positive and 100 negative cases;
- 9-months post-initiation of distribution: a minimum of 35 additional positives and 450 additional negative cases, or the remaining balance of the total enrollment caps for the positive and negative cases, whichever are less; and
- 12-month post-initiation of distribution: the remaining balance of the total enrollment caps for the positive and negative cases.

The agreed upon study plan may be revised subject to concurrence of OHT2/OPEQ/CDRH.

F. Tiger Tech Solutions must have a process in place to collect information on the continued appropriate use and performance of the Tiger Tech COVID Plus Monitor at organizations that do not participate in the additional clinical performance study specified in Condition E above during execution of the additional clinical performance study and at all organizations following completion of the additional clinical performance study, including information regarding comparative outcomes against FDA-authorized COVID-19 RT-PCR tests, when available.

G. Tiger Tech Solutions must notify FDA of any authorized distributor(s)[11] of the Tiger Tech COVID Plus Monitor, including the name, address, and phone number of any authorized distributor(s), and provide authorized distributor(s) with a copy of this EUA and any updates.

Tiger Tech Solutions and any Authorized Distributor(s)

H. Tiger Tech Solutions and authorized distributors must distribute the authorized Tiger Tech COVID Plus Monitor with the authorized labeling only to organizations with personnel who are adequately equipped, trained, and capable of using the Tiger Tech COVID Plus Monitor in accordance with the authorized labeling.

I. Tiger Tech Solutions and authorized distributors must make authorized labeling available on their website.

[11] "Authorized Distributor(s)" are identified by Tiger Tech Solutions in an EUA submission as an entity allowed to distribute the device.

J. Authorized distributors must make Tiger Tech Solutions aware of any adverse events of which they become aware.

K. Through a process of inventory control, Tiger Tech Solutions and authorized distributors must maintain records of the organizations to which they distribute the Tiger Tech COVID Plus Monitor and the number of products they distribute.

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

M. Tiger Tech Solutions and authorized distributor(s) must ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records must be made available to FDA for inspection upon request.

End-user facilities

N. End-user facilities using the authorized Tiger Tech COVID Plus Monitor must make available to recipients the accompanying Fact Sheet for Recipients and make available to users the accompanying Fact Sheet for Users.

O. End-user facilities must ensure users using the Tiger Tech COVID Plus Monitor are adequately equipped, trained, and capable, and users must maintain records of device usage including:

- Usage location
- Name of user
- Total number of recipients
- Total number of recipients with a “red light” indicator
- Names of recipients (for non-visitors to the end-user facility only, such as employees and students)
- Results of the same-day RT-PCR tests on the recipients, if available (for non-visitor recipients of the end-user facility only)

Conditions Related to Printed Materials, Advertising, and Promotion

P. All descriptive printed matter, advertising, and promotional materials relating to the use of the authorized Tiger Tech COVID Plus Monitor 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) and (q)(1) and (r) of the Act and FDA implementing regulations.

Q. No descriptive printed matter, advertising, or promotional materials relating to the use of the authorized Tiger Tech COVID Plus Monitor may represent or suggest that the authorized Tiger Tech COVID Plus Monitor is safe or effective for preventing exposure

to and spread of SARS-CoV-2 by identifying certain biomarkers in asymptomatic individuals over the age of 5.

R. All descriptive printed matter, advertising, and promotional materials relating to the use of the authorized Tiger Tech COVID Plus Monitor shall clearly and conspicuously state that:

- The Tiger Tech COVID Plus Monitor has neither been cleared nor approved by FDA, but has been authorized by FDA under an EUA for emergency use by trained personnel to help prevent exposure to and spread of SARS-CoV-2 by identifying certain biomarkers in asymptomatic individuals over the age of 5, when performed following a temperature reading that does not meet the criteria for fever in settings where temperature check is being conducted in accordance with CDC and local institutional infection prevention and control guidelines; and

- The emergency use of the Tiger Tech COVID Plus Monitor is authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of 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 declaration is terminated or authorization is revoked sooner.

S. All descriptive printed matter, advertising, and promotional materials relating to use of the Tiger Tech COVID Plus Monitor must include the following warning:

WARNING:

- The Tiger Tech COVID Plus Monitor is NOT a diagnostic device, and must not be used to diagnose or exclude SARS-CoV-2 infection.

- Use of the Tiger Tech COVID Plus Monitor in an asymptomatic population is intended to be part of an infection control plan that includes uses of a thermometer. A “red light” indicator from the Tiger Tech COVID Plus Monitor does not necessarily indicate current SARS-CoV-2 infection. Instead, it is only an indication – like a fever – that a person is demonstrating certain biomarkers of certain conditions, such as hypercoagulation, that may be associated with SARS-CoV-2 infection. As such, this device is only for use as a preventative screening tool.

V. Duration of Authorization

This EUA will be effective until the declaration that circumstances exist justifying this authorization 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

Enclosures