June 30, 2021

Tidal Medical Technologies LLC
Mr. George Hattub
2024 W 15th Street #F336
Plano, TX 75075

Dear Mr. Hattub:

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 InSee incentive spirometer accessory (hereafter "InSee") for quantitatively tracking patient usage[1] of Vyaire Medical's AirLife incentive spirometer[2] as an aid in treatment of respiratory conditions by patients with Coronavirus Disease 2019 (COVID-19) in hospital settings.

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]

There are no FDA approved or cleared devices for quantitatively tracking patient usage of spirometers as an aid in treatment of respiratory conditions by patients with COVID-19 in hospital settings. Generally, incentive spirometers are used during recovery of respiratory illness (e.g., COVID-19) to strengthen the muscles used for breathing and increase ventilation. Use of InSee in conjunction with an incentive spirometer may assist in treating COVID-19 respiratory conditions and improve clinical outcomes by monitoring and encouraging more frequent and consistent usage of the spirometer, without reliance on the presence of the healthcare provider or reliance on the patient's memory and reporting for use of the spirometer. Despite the authorized use being limited to Vyaire Medical AirLife incentive spirometer, authorization of InSee may be

[1] Quantification of patient usage includes spirometer attempts, successes, and volumetric goals when a patient uses the Vyaire Medical's AirLife incentive spirometer.
[2] The InSee is a third-party accessory that is **only** compatible with Vyaire Medical's AirLife incentive spirometer and is not compatible with other incentive spirometers.
[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 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).

used broadly because Vyaire Medical AirLife incentive spirometers comprise almost half of the incentive spirometers used in U.S. acute care hospitals. Bench performance testing of InSee demonstrated 97% accuracy of the spirometer measurements. Based the totality of scientific evidence available, FDA has concluded that the InSee may be effective at quantitatively tracking patient usage of Vyaire Medical's AirLife incentive spirometer as an aid in treatment of respiratory conditions by patients with COVID-19 in hospital settings.

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 InSee, 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 InSee, 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 InSee may be effective in treating respiratory conditions in patients with COVID-19 in hospital settings by quantitatively tracking patient usage of Vyaire Medical's AirLife incentive spirometer, and that the known and potential benefits of such product, when used for treating COVID-19, outweigh the known and potential risks of InSee; and,

3. There is no adequate, approved, and available alternative to the emergency use of the InSee for treating COVID-19 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 emergency use of the InSee for treating respiratory conditions in patients with COVID-19 in a hospital setting by quantitatively tracking patient usage of Vyaire Medical's AirLife incentive spirometer.

The InSee is contraindicated and not authorized for use in patients with recent eye surgery, a pneumothorax, and an aneurysm in their brain, chest, or abdomen.

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

The Authorized InSee

The InSee is an incentive spirometer accessory that quantitatively tracks patient usage of Vyaire Medical's AirLife incentive spirometer. Quantification of patient usage includes spirometer attempts, successes, and volumetric goals when a patient uses the Vyaire Medical's AirLife incentive spirometer.

The InSee uses an infrared sensor, which monitors the movement of the spirometer's internal cylinder. The cylinder contains a piston whose movement measures the volume of air that is inhaled. Using time-of-flight calculations, cylinder movement is converted to tidal volume, which is the volume of air moved with each breath and is a key marker of respiratory function. The data the InSee device collects is stored and is displayed on the bottom of the InSee. A healthcare practitioner sets a target tidal volume for the patient before use. While sitting upright, the patient puts the mouthpiece of the incentive spirometer in their mouth and closes their lips tightly around it. The patient then slowly exhales and inhales as deeply as possible. The patient must breathe through their mouth or else the spirometer and InSee device will not function. As the patient uses the spirometer, the InSee measures the tidal volume and determines how many times a patient failed to reach the target tidal volume that was programmed in the InSee. It also determines the maximum tidal volume the patient was able to reach, with an alarm indicating success. In addition, there is a set timer internal to the InSee that reminds the patient to use the spirometer and InSee via a blinking red LED and alarm that activates every 10 minutes (which can be adjusted by the healthcare provider). This alarm stops once the patient uses the spirometer and InSee. Lastly, there is an option that can be set where a blinking green LED and a success alarm activate when a "goal" is met. This alarm of success is different than the alarm of inactivity.

The InSee is comprised of the following components:

- The InSee incentive spirometer accessory
- USB-C charging cable

The InSee requires the following components, which are not provided:

- Vyaire Medical AirLife incentive spirometer

The above described InSee device, is authorized to be accompanied with labeling, entitled "InSee Device User Manual" (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 healthcare providers and healthcare facilities, respectively:

- Fact Sheet for Healthcare Providers: Emergency Use of the InSee Incentive Spirometer Accessory

- Fact Sheet for Patients: Emergency Use of the InSee Incentive Spirometer Accessory

The above described product, when accompanied with Tidal Medical Technologies LLC's developed Instructions For Use (identified above) and the two Fact Sheets (collectively 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 InSee, 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 InSee may be effective in the treatment of COVID-19, 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 InSee, 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 InSee 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 InSee 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 InSee device 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:

Tidal Medical Technologies LLC

A. Tidal Medical Technologies LLC must comply with the labeling requirements under 21 CFR 801 Subpart A (general labeling provisions) and 21 CFR 801.109 (labeling for prescription devices), as well as those described in Section II of this letter, Scope of Authorization. Compliance with unique device identification regulations (see Subpart B of 21 CFR Part 801) is not required under this EUA.

B. Tidal Medical Technologies LLC must make the InSee available with the authorized labeling.

C. Tidal Medical Technologies LLC may request changes to this EUA for the InSee device, including changes to the authorized labeling. Any requests for changes to this EUA must be submitted to the Office of Health Technology 1 (OHT1)/Office of Product Evaluation and Quality (OPEQ)/Center for Devices and Radiological Health (CDRH). Such changes require appropriate authorization from FDA prior to implementation.[6]

D. Tidal Medical Technologies LLC 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. Tidal Medical Technologies LLC must establish a process to collect adverse event information from healthcare facility customers.

E. Tidal Medical Technologies LLC must notify FDA of any authorized distributor(s)[7] of the InSee, 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.

Tidal Medical Technologies LLC, and any Authorized Distributor(s)

F. Tidal Medical Technologies LLC, and authorized distributors must distribute the authorized InSee with the authorized labeling only to healthcare facilities with healthcare providers who are adequately capable of using the InSee in conjunction with the incentive spirometer in accordance with the authorized labeling.

G. Tidal Medical Technologies LLC, and authorized distributors must make authorized labeling available on their websites.

[6] 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 OHT1/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.

[7] "Authorized Distributor(s)" are identified by Tidal Medical Technologies LLC in an EUA submission as an entity allowed to distribute the device.

H. Authorized distributors must make Tidal Medical Technologies LLC aware of any adverse events of which they become aware.

I. Through a process of inventory control, Tidal Medical Technologies LLC and authorized distributors must maintain records of the healthcare facilities to which they distribute the InSee and the number of each product they distribute.

J. Tidal Medical Technologies LLC 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.

K. Tidal Medical Technologies LLC 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.

Healthcare Facilities

L. Healthcare facilities using the authorized InSee must make available to patients the accompanying Fact Sheet for Patients and make available to healthcare providers the accompanying Fact Sheet for Healthcare Providers.

M. Healthcare facilities using the InSee must make Tidal Medical Technologies LLC, and FDA aware of any adverse events under 21 CFR Part 803.

N. Healthcare facilities must ensure healthcare providers using the InSee are adequately equipped, trained, and capable, and must maintain records of device usage.

Conditions Related to Printed Materials, Advertising, and Promotion

O. All descriptive printed matter, advertising, and promotional materials relating to the use of the authorized InSee under this authorization shall be consistent with the authorized labeling, as well as the terms set forth in this EUA, and meet the applicable requirements set forth in section 502(a) and (q)(1) and (r) of the Act, as applicable, and FDA implementing regulations.

P. No descriptive printed matter, advertising, or promotional materials relating to the use of the authorized InSee may represent or suggest that this product is safe or effective for quantitatively tracking patient usage of Vyaire Medical's AirLife incentive spirometer as an aid in treatment of respiratory conditions or treatment of COVID-19.

Q. All descriptive printed matter, advertising, and promotional materials relating to the use of the authorized InSee shall clearly and conspicuously state that:

- The InSee has neither been cleared nor approved by the FDA, but has been authorized by FDA under an EUA for quantitatively tracking patient usage of Vyaire Medical's AirLife incentive spirometer as an aid in treatment of respiratory conditions during the COVID-19 pandemic; and

- The emergency use of the InSee 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 authorization is terminated or authorization is revoked sooner.

V. Duration of Authorization

This EUA will be effective until the declaration that circumstances exist justifying the authorization of the InSee is terminated under section 564(b)(2) of the Act or the EUA is revoked under section 564(g) of the Act.

Sincerely,

_____

RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

Enclosures