



April 26, 2020

Cynthia Merrell
Vice President, Quality and Regulatory
VitalConnect, Inc.
224 Airport Parkway, Suite 300
San Jose, CA 95110 US

Dear Ms. Merrell:

This letter is in response to your request that the U.S. Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for the VitalPatch Biosensor (“VitalPatch”)¹ intended to be used by healthcare professionals (HCP) in the hospital setting for remote monitoring and detection of changes in the QT interval of an electrocardiogram (ECG) in general care² patients who are 18 years of age or older (“patients”)³ and are undergoing treatment for Coronavirus Disease 2019 (COVID-19) with drugs that can prolong QT intervals and may cause life threatening arrhythmias (e.g., hydroxychloroquine or chloroquine, especially when used in combination with azithromycin). Such remote monitoring may reduce HCP exposure to SARS-CoV-2, the virus that causes COVID-19.

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-19.⁴ 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, including alternative products used as medical devices, pursuant to section 564 of the FD&C Act, subject to the terms of any authorization issued under that section.⁵

¹ The VitalPatch is 510(k)-cleared (most recently in K192757) as a wireless remote monitoring system for continuous collection of physiological data in home and healthcare settings, including heart rate, ECG, heart rate variability, R-R interval, respiratory rate, body temperature, skin temperature, activity (including step count), and posture (body position relative to gravity including fall). This EUA authorizes the emergency use of the VitalPatch to include automated arrhythmia detection of the QT interval of an ECG, a function not included in the 510(k)-cleared device, for patients undergoing treatment in a hospital setting for COVID-19 with drugs that can prolong QT intervals and may cause life-threatening arrhythmias.

² “General care patients” refer to patients that are not in the intensive care unit (non-ICU).

³ “Patients,” when used in this letter, refer to general care patients that are 18 years of age or older.

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 4, 2020) (accessible at <https://www.fda.gov/media/135010/download>).

⁵ U.S. Department of Health and Human Services, *Declaration that Circumstances Exist Justifying Authorizations*

FDA consulted with subject matter experts within HHS on the public health needs for vital sign and ECG monitoring for complications related to COVID-19 or its treatment (such as QT prolongation). While there are alternative FDA-approved, cleared devices for remote monitoring and detection (e.g., bedside monitors, ECG telemetry units), there are no adequate FDA approved, licensed, or cleared devices for remote patient monitoring and detection of QT interval changes in ECG for patients who are undergoing treatment for COVID-19 with drugs that may cause life-threatening arrhythmias.

Proposed treatments for COVID-19 include the use of drugs that can prolong QT intervals and may cause life threatening arrhythmias (e.g., hydroxychloroquine or chloroquine, especially when used in combination with azithromycin). Common methods to identify those patients rely on monitoring the QT interval of an ECG during drug administration. The QT interval is usually measured on a 12-lead ECG at various timepoints during drug exposures. However, the use of 12-lead ECG recorders on patients that are being treated for COVID-19 is burdensome and may present additional risk to patients and HCPs due to the need for in-person consultations, as well as the need to sanitize the equipment between patients and additional personal protective equipment usage.

Based on bench testing and reported clinical experience, FDA has concluded that the VitalPatch may be effective for remotely monitoring and detecting the QT interval of an ECG in patients who are undergoing treatment in a hospital setting for COVID-19 with drugs that can prolong QT intervals and may cause life threatening arrhythmias (e.g., hydroxychloroquine or chloroquine, especially when used in combination with azithromycin). In addition, remote monitoring may reduce the HCP risk of exposure to SARS-CoV-2 during the COVID-19 pandemic.

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 VitalPatch, as described in the Scope of Authorization section of this letter (Section II) and pursuant to the Conditions of Authorization (Section III) of this letter.

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of the VitalPatch, as described in the Scope of Authorization (Section II) of this letter, for remote monitoring and detection of QT interval changes in ECG for patients who are undergoing treatment in a hospital setting for COVID-19 with drugs that can prolong QT intervals and may cause life threatening arrhythmias (e.g., hydroxychloroquine or chloroquine, especially when used in combination with azithromycin), meets the criteria for issuance of an authorization under section 564(c) of the Act, because I have concluded that:

1. 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 the VitalPatch may be effective in remotely monitoring and detecting QT interval changes of an ECG in patients who are undergoing treatment in a hospital setting for COVID-19 with drugs that can prolong QT intervals and may cause life threatening arrhythmias (e.g., hydroxychloroquine or chloroquine, especially when used in combination with azithromycin). The known and potential benefits of VitalPatch, for such use, outweigh the known and potential risks; and
3. There is no adequate, approved, and available alternative to the emergency use of the VitalPatch for remote monitoring and detection of QT interval changes of an ECG in patients who are undergoing treatment in a hospital setting for COVID-19 with drugs that can prolong QT intervals and may cause life threatening arrhythmias (e.g., hydroxychloroquine or chloroquine, especially when used in combination with azithromycin).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 use of the VitalPatch by HCP in a hospital setting for remote monitoring and detection of changes in the QT interval of an ECG in general care patients who are 18 years of age or older and are undergoing treatment for COVID-19 with drugs that can prolong QT intervals and may cause life threatening arrhythmias (e.g., hydroxychloroquine or chloroquine, especially when used in combination with azithromycin). Such remote monitoring may reduce HCP exposure to SARS-CoV-2. The VitalPatch is not intended for use on critical care patients. The VitalPatch should not be used during a magnetic resonance imaging (MRI) scan or in a location where it will be exposed to strong electromagnetic forces. The VitalPatch is not intended for use as a stand-alone diagnostic monitor for detection of changes in vital signs. The VitalPatch is not intended to detect life-threatening abnormal heart rhythms. Use of the VitalPatch while showering should be minimized to avoid direct exposure under the shower head, excessive contact with soap, or scrubbing. The VitalPatch is not intended to be submerged or used in a sauna.

The Authorized VitalPatch

The VitalPatch is a wireless remote monitoring system that is FDA-cleared for use by HCPs for continuous collection of physiological data in home and healthcare settings. The VitalPatch device is intended to be integrated with a patient monitoring platform where data is transmitted wirelessly from the device to the patient monitoring platform for storage and analysis. The VitalPatch can be used on one (1) patient and lasts for up to seven (7) days of continuous vital sign monitoring and is then disposed of at the end of the monitoring session.

⁶ No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the Act.

The VitalPatch employs an automated arrhythmia detection algorithm that, in addition to its FDA-cleared uses, can analyze the QT interval of an ECG.

The VitalPatch contains the following components:

- The VitalPatch, provided in a sealed pouch.

The VitalPatch also requires the following components, which are not provided with the remote monitoring tool, but were cleared as part of a previous 510(k) submission (K170973):

- VistaTablet Device – a handheld mobile relay device that securely hosts and transmits the vital signs measured by the VitalPatch, presenting this data locally for the patient and to HCP. The VistaTablet Device integrates a touch-screen computer and a cellular or Wi-Fi data connection to collect VitalPatch data. The patient keeps the VistaTablet device with them at all times, allowing continuous upload of biosensor data to the VitalCloud.
- VistaPoint Application – a software Graphical User Interface intended for use by HCP to display physiological data collected by the VitalPatch.
- VistaCenter Application – a web application that runs in a computer web browser or mobile device. This allows HCP to monitor patients from multiple VitalPatch devices in a single user interface.
- VitalCloud – stores data uploaded by the VistaPoint Application and makes it available to cloud-enabled monitoring and data analytics applications, such as the VistaCenter Application.

The above described VitalPatch is authorized to be accompanied with labeling entitled “Instructions for Use, VitalPatch Biosensor” (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 HCP and healthcare facilities, respectively:

- Fact Sheet for Healthcare Providers: VitalPatch Biosensor
- Fact Sheet for Patients: VitalPatch Biosensor

The above described product, when accompanied with the sponsor’s developed 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 VitalPatch, 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 VitalPatch may be effective in remote monitoring and detection of changes in the QT interval of an ECG in patients who are undergoing treatment in a hospital setting for COVID-19 with drugs that can prolong QT intervals and may cause life threatening arrhythmias (e.g., hydroxychloroquine or chloroquine, especially when used in combination with azithromycin). Such remote monitoring may reduce HCP exposure to 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 VitalPatch, 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 authorized VitalPatch 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 III). 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) described above and the Secretary of HHS's corresponding declaration under section 564(b)(1), the VitalPatch described above is authorized for remote monitoring and detection of changes in the QT interval of an ECG in patients who are undergoing treatment in a hospital setting for COVID-19 with drugs that can prolong QT intervals and may cause life threatening arrhythmias (e.g., hydroxychloroquine or chloroquine, especially when used in combination with azithromycin), and such remote monitoring may reduce HCP exposure to SARS-CoV-2.

III. Conditions of Authorization

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

VitalConnect, Inc., as Sponsor of Authorized Product

- A. VitalConnect, Inc. 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. As such, compliance with unique device identification regulations (see Subpart B of 21 CFR Part 801) is not required under this EUA.
- B. VitalConnect, Inc. will make the VitalPatch available with authorized labeling. VitalConnect, Inc. may request changes to the authorized labeling. Such changes require review and concurrence from OHT2/OPEQ/CDRH.
- C. VitalConnect, Inc. may request changes to the Scope of Authorization (Section II in this letter) of the authorized VitalPatch. Such requests will be made by VitalConnect, Inc., in consultation with and require concurrence of OHT2/OPEQ/CDRH and the Office of Counterterrorism and Emerging Threats (OCET)/Office of the Chief Scientist

(OCS)/Office of the Commissioner (OC).

- D. VitalConnect, Inc. may request changes to any components or materials. Such requests will be made in consultation with and require concurrence of OHT2/OPEQ/CDRH.
- E. VitalConnect, Inc. will have process in place for reporting, and will report to FDA, adverse events of which they become aware to FDA under 21 CFR Part 803. VitalConnect, Inc. will establish a process to collect adverse event information from healthcare facility customers.
- F. VitalConnect, Inc. will notify FDA of any authorized distributor(s)⁷ of the VitalPatch, 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.

VitalConnect, Inc., and any Authorized Distributor(s)

- G. VitalConnect, Inc., and authorized distributors will distribute the authorized VitalPatch with the authorized labeling only to healthcare facilities with HCP who are adequately equipped, trained, and capable of using the VitalPatch according to the criteria set forth by VitalConnect, Inc.
- H. VitalConnect, Inc., and authorized distributors will make authorized labeling available on their websites.
- I. Authorized distributors will make VitalConnect, Inc. aware of any adverse events of which they become aware.
- J. Through a process of inventory control, VitalConnect, Inc. and authorized distributors will maintain records of the healthcare facilities to which they distribute the VitalPatch and the number of each product they distribute.
- K. VitalConnect, Inc. 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.
- L. VitalConnect, Inc. and authorized distributor(s) will ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request.

Healthcare Facilities

- M. Healthcare facilities using the authorized VitalPatch must make available to patients the

⁷ “Authorized Distributor(s)” are identified by VitalConnect, Inc. in an EUA submission as an entity allowed to distribute the device.

accompanying Patient Fact Sheet and make available to HCP the accompanying Healthcare Provider Fact Sheet. Healthcare facilities using the authorized VitalPatch must also make available the Instructions for use for the VitalPatch to patients and HCP.

- N. Healthcare facilities using the VitalPatch must make VitalConnect, Inc. and FDA aware of any adverse events under 21 CFR Part 803.
- O. Healthcare facilities will ensure healthcare providers using the VitalPatch are adequately equipped, trained, capable, and will maintain records of device usage.

Conditions Related to Advertising and Promotion

- P. All descriptive printed matter, including advertising and promotional materials, relating to the use of the authorized VitalPatch 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.
- Q. No descriptive printed matter, including advertising or promotional materials, relating to the use of the authorized VitalPatch may represent or suggest that this product is safe or effective for remote monitoring of changes in the QT interval of an ECG in patients who are undergoing treatment of COVID-19.
- R. All descriptive printed matter, including advertising and promotional materials, relating to the use of the authorized VitalPatch shall clearly and conspicuously state that:
 - The VitalPatch has neither been cleared or approved for remote monitoring and detection of changes in the QT interval of an ECG in patients who are undergoing treatment in a hospital setting for COVID-19 with drugs that can prolong QT intervals and may cause life threatening arrhythmias (e.g., hydroxychloroquine or chloroquine, especially when used in combination with azithromycin). Such remote monitoring may reduce HCP exposure to SARS-CoV-2;
 - The VitalPatch has been authorized for the above emergency use by FDA under an EUA;
 - The VitalPatch has been authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of medical devices under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

V. Duration of Authorization

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