May 14, 2020

Mr. Nir Geva
CTO & Business Development
G Medical Innovations Ltd.
5 Oppenheimer Str.
Rehovot 7670105
Israel

Dear Mr. Geva:

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 G Medical VSMS ECG Patch[1] (hereafter "VSMS Patch") intended to be used by healthcare professionals (HCP) in the hospital setting for remote monitoring of the QT interval of an electrocardiogram (ECG) in general care[2] 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, due to shortages during the COVID-19 outbreak, pursuant to section 564 of the FD&C Act, subject to the terms of any authorization issued under that section.[5]

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[1] The VSMS Patch was granted, under the trade name "VSMS Holter monitor," the European CE Mark in 2017 for home use in patients who experience transient symptoms that may suggest cardiac arrhythmia. The VSMS Patch is not FDA-cleared or -approved.
[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 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).

FDA consulted with subject matter experts within HHS on the public health need for remote ECG monitoring for drug-induced QT interval prolongation in patients that are undergoing treatment for COVID-19. While alternate FDA-approved or cleared devices for remote ECG monitoring exist, those may not measure the QT interval and/or may not be adequately available during the COVID-19 outbreak. Additionally, alternate FDA-approved or cleared devices for recording the QT interval may not offer remote monitoring capabilities to reduce HCP exposure to SARS-CoV-2 and/or may not be adequately available during the COVID-19 emergency.

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 HCP 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 design verification, validation studies performed, and reported clinical experience, including its related clinical utility for home use in patients who experience transient symptoms that may suggest cardiac arrhythmia in Europe and Israel, FDA has concluded that the VSMS Patch may be effective for remote monitoring of 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 VSMS Patch, as described in the Scope of Authorization section of this letter (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 VSMS Patch, as described in the Scope of Authorization (Section II) of this letter, for remote monitoring of the QT interval 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 VSMS Patch may be effective in remotely monitoring QT interval prolongation on 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 the VSMS Patch, 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 VSMS Patch for remote monitoring of 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).[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 VSMS Patch by HCP in a hospital setting for remote monitoring of the QT interval of an ECG in general care patients who are 18 years of age or older and 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 the HCP risk of exposure to SARS-CoV-2.

The VSMS Patch does not provide continuous monitoring of the QT interval of an ECG. The VSMS Patch is not intended for use on critical care patients. The VSMS Patch 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 VSMS Patch is not intended for use as a stand-alone diagnostic monitor for detection of changes in an ECG. The VSMS Patch is not intended to detect life-threatening abnormal heart rhythms. The VSMS Patch is not intended for use during external defibrillation procedures (such use may cause the defibrillator's discharge pulse to be ineffective for the patient). The VSMS Patch is not intended for use on patients with unhealed surgical incisions/dressings on the thoracic regions. The VSMS Patch is not intended for use on patients with skin or soft tissue damage in the area where the VSMS Patch is placed (such as burns, irritation, infections, wounds, etc.).

The Authorized VSMS Patch

The VSMS Patch is intended for use by HCP for remote monitoring of the QT interval of an ECG in patients who 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.

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

The VSMS Patch is a 2-lead ECG event monitor with an additional calculated lead. The system comprises an adhesive patch with a reusable recorder attached to it and a smartphone. The VSMS Patch is applied to the patient's upper left chest. The VSMS Patch can be used on one (1) patient for up to fourteen (14) days of ECG monitoring and must then be replaced. It records and transmits the ECG data to the smartphone. The length of event recording and the frequency of data transmission are set by the healthcare provider. The default is to record and transmit 10 minutes of ECG data every 1 hour. The data are saved and wirelessly transmitted by the smartphone to the G Medical Diagnostics Call Center for QT analysis. A call center certified cardiographic technician will compile the clinical findings and send the report to the prescribing physician at the hospital.

The VSMS Patch is comprised of the following components:

- VSMS physical patches (disposable)
- VSMS patch recorder (reusable)
- Android based smartphone with charger
- Shaving razor
- Alcohol pads
- Adhesive removal pads

The above described VSMS Patch, is authorized to be accompanied with labeling, entitled "G Medical Innovations VSMS ECG Patch Professional User Guide" and "VSMS ECG Patch Quick Start Guide" (collectively referred to as "Instructions For Use" that will be 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 patients, respectively:

- Fact Sheet for Healthcare Providers: G Medical VSMS ECG Patch
- Fact Sheet for Patients: G Medical VSMS ECG Patch

The above described product, when accompanied with the 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 VSMS Patch 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 VSMS Patch may be effective for remote monitoring of 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 VSMS Patch, 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 VSMS Patch 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) described above and the Secretary of HHS's corresponding declaration under section 564(b)(1), the VSMS Patch described above is authorized for use by HCP for remote monitoring of 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. Waiver of Certain FDA Requirements

Pursuant to Section 564(e)(3) of the Act, with respect to the emergency use of a product for which an authorization under this section is issued, FDA may waive or limit, to the extent appropriate given the circumstances of the emergency, requirements regarding good manufacturing practice otherwise applicable to the manufacture, processing, packing, or holding of products subject to regulations under this Act, including such requirements established under section 520(f)(1). FDA grants that waiver, including the quality system requirements under 21 CFR 820.

IV. Conditions of Authorization

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

<u>G Medical Innovations Ltd., as Sponsor of Authorized Product</u>

A. G Medical Innovations Ltd. 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. G Medical Innovations Ltd. will make the VSMS Patch available with authorized labeling. G Medical Innovations Ltd. may request changes to the authorized labeling. Such changes require review and concurrence from Office of Health Technology 2

(OHT2)/Office of Product Evaluation and Quality (OPEQ)/Center for Devices and Radiological Health (CDRH).

C. G Medical Innovations Ltd. may request changes to the Scope of Authorization (Section II in this letter) of the authorized VSMS Patch. Such requests will be made by G Medical Innovations Ltd., 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. G Medical Innovations Ltd. may request changes to any components or materials. Such requests will be made in consultation with and require concurrence of OHT2/OPEQ/CDRH.

E. G Medical Innovations Ltd. will have process in place for reporting adverse events, of which they become aware, and will report such events to FDA under 21 CFR Part 803. G Medical Innovations Ltd. will establish a process to collect adverse event information from healthcare facility customers.

F. G Medical Innovations Ltd. will notify FDA of any authorized distributor(s)[7] of the VSMS Patch, 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.

G Medical Innovations Ltd., and any Authorized Distributor(s)

G. G Medical Innovations Ltd., and authorized distributors will distribute the authorized VSMS Patch with the authorized labeling only to healthcare facilities with HCP who are adequately equipped, trained, and capable of using the VSMS Patch according to the criteria set forth by G Medical Innovations Ltd.

H. G Medical Innovations Ltd. and authorized distributors will make authorized labeling available on their websites.

I. Authorized distributors will make G Medical Innovations Ltd. aware of any adverse events of which they become aware.

J. Through a process of inventory control, G Medical Innovations Ltd. and authorized distributors will maintain records of the healthcare facilities to which they distribute the VSMS Patch and the number of each product they distribute.

K. G Medical Innovations Ltd. and authorized distributor(s) are authorized to make available additional information relating to the emergency use of the product that is

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

consistent with, and does not exceed, the terms of this letter of authorization.

L. G Medical Innovations Ltd. 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 VSMS Patch must make available to patients the accompanying Patient Fact Sheet and make available to HCP the accompanying Healthcare Provider Fact Sheet.

N. Healthcare facilities using the VSMS Patch must make G Medical Innovations Ltd. and FDA aware of any adverse events under 21 CFR Part 803.

O. Healthcare facilities will ensure HCP using the VSMS Patch are adequately equipped, trained, capable, and will maintain records of product usage.

Conditions Related to Printed Materials, Advertising and Promotion

P. All descriptive printed matter, including advertising and promotional materials, relating to the use of the authorized VSMS Patch 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 VSMS Patch may represent or suggest that this product is safe or effective for remote monitoring of 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 VSMS Patch shall clearly and conspicuously state that:

- The VSMS Patch has neither been cleared or approved for the indication to assist in remote monitoring of 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).

- The VSMS Patch has been authorized for the above emergency use by FDA under an EUA.

- The VSMS Patch 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,

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RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

Enclosures