G Medical Innovations Holdings Ltd
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FDA grants Prizma Over-the-Counter (OTC) Authorisation in USA

- **Prizma licensed as a non-prescription over-the-counter (OTC) medical device by US Food and Drug Administration**
- **FDA grants OTC authorisation based on Policy for COVID-19 Public Health Emergency**
- **Allows Prizma device to be sold directly to consumers without a prescription**
- **Unlocks a significantly large opportunity in the US Market – GMV well placed to capitalise in the near term**
- **Commercial negotiations to expedite market penetration underway**

Mobile and e-Health company **G Medical Innovations Holdings Limited (ASX:GMV) ("G Medical" "the Company")**, is pleased to advise that it has been granted Over-the-counter (OTC) authoisation for its Prizma device by the US Food & Drug Administration (FDA).

As previously advised the Company has been undergoing FDA submissions seeking to extend Prizma's existing FDA 510(K) Class II medical devices approval (granted and announced to the ASX on 4 September 2017) to "Over-the-Counter" ("OTC") (also referred to as non-prescription designation) authorisation.

On 20 March 2020, the FDA issued a guidance document ("Policy") in response to the COVID-19 US public health emergency titled "Enforcement Policy for Non-Invasive Remote Monitoring Devices Used to Support Patient Monitoring During the Coronavirus Disease-2019 (COVID-19) Public Health Emergency" [1].

In consideration of the FDA COVID-19 Policy, the Company directly contacted the FDA seeking acknowledgment that the Prizma medical device satisfied the Policy scope for authorisation defined as "non-invasive remote monitoring devices that measure or detect common physiological parameters and that are used to support patient monitoring during the COVID-19 public health emergency" [1].

The Company is very pleased to confirm to its shareholders that the FDA confirmed that the Company's "proposed change to expand the use of the Prizma device from RX (Prescription) to OTC meets the criteria of the Remote Monitoring guidance document (Policy)" [FDA]; and that the clearance is not temporary, despite the authorisation being issued with specific application to, and in consideration of the COVID-19 Policy.

In accordance with the FDA Policy, the Prizma's medically certified technology has been acknowledged and qualified specifically that "in respect of the COVID-19 public health emergency, the leveraging of current non-invasive patient monitoring technology will help eliminate unnecessary patient contact and ease the burden on hospitals, other health care facilities, and health care professionals that are experiencing increased demand due to the COVID-19 pandemic as it relates to diagnosis and treatment of patients with COVID-19 and ensuring other patients who require monitoring for conditions unrelated to COVID19 can be monitored outside of health care facilities." [1]

The Prizma further qualified within the Policy criteria specifically in accordance with the Policy's "Scope" [1];

1. "non-invasive monitoring device(s) have the potential to be connected to a wireless network through Bluetooth, Wi-Fi, or cellular connection to transmit a patient's measurements directly to their health care provider or other monitoring entity;
2. devices also have the potential to apply algorithms to transform a patient's physiological parameters into a novel index or alarm that may aid a health care professional in the diagnosis of a particular condition or disease state/severity." [1]

Further, the Prizma's medically certified technology satisfied the Policy's "Modifications to FDA-Cleared Indications, Claims, or Functionality" [1];

1. "The device is intended for the purpose of displaying, printing or analyzing the physiological parameter(s) measured by the device; and
2. The device is intended for the purpose of supporting or providing adjunctive recommendations to the health care professional or patient about prevention, diagnosis or treatment of COVID-19 or co-existing conditions; and
3. The health care provider and/or patient can independently review the basis for any diagnostic or treatment recommendations." [1]

Prizma's OTC Clearance in the US Market

Securing FDA OTC authorisation for the Prizma is a significant achievement for G Medical, as it allows for its Prizma device to be sold directly to consumers without a prescription.

Prizma is a medically certified device, used by every day consumers to monitor vital signs including temperature, heart rate, stress levels, SPO_2 (blood oxygen saturation) and electrocardiography (ECG). All of which are physiological biometrics that can be measured to detect symptoms associated with infection and chronic illness.

The Company believes the Prizma device has the ability to assist in alleviating pressure on the US healthcare systems, which is undergoing capacity challenges directly related to the COVID-19 public health emergency. Further, the Prizma can assist in the management of unrelated medical conditions which provide additional burden on the healthcare system and its professionals. In consideration of this, G Medical is confident that the Prizma will be well received by consumers given the current conditions, as well as future benefit as the US pushes further towards seeking and adopting telehealth solutions, particularly those that can provide out-of-clinic and isolated vital signs monitoring requirements.

The US is a large addressable market and provides G Medical with a tremendous opportunity. The Company is in ongoing discussions with a number of parties to expedite a broader consumer focused launch.

CEO and Executive Director Dr Yacov Geva said: "FDA OTC authorisation is a monumental development for G Medical and provides us with direct access to consumers, physicians and healthcare providers who are currently in need of our solutions. We are confident that the product will be well received and can hopefully assist in reducing the burden on the healthcare system, which is currently inundated.

"G Medical is currently delineating a number of ways to penetrate the US consumer market and looks forward to updating shareholders on progress in the near term."

In accordance with Policy, additional disclosures on the Prizma's packaging will consider the following elements (where relevant) [1]:

1. A clear description of the available data on the device's new indications, claims, or functions related to COVID-19 or co-existing conditions, including:
    a. Device performance;
    b. Method of determining any diagnostic or treatment recommendations; and
    c. Potential risks.
2. A prominent notice to both the patient and health care provider that recommendations provided by the device are adjunctive (supporting) and should not be solely or primarily relied upon to prevent, diagnose, or treat COVID-19 or co-existing conditions.
3. Information on use conditions, in particular whether the device is intended for spot-checking, trend monitoring, or continuous monitoring.
4. Clear distinction delineating FDA-cleared indications and claims from those that are not FDA-cleared. In addition, FDA recommends the labeling include a general statement about changes that have not been cleared by FDA.
5. For devices previously cleared for use only in a hospital or other health care facility and for which the environment of use has been expanded to include in-home use, adequate instructions for use in the home setting with appropriate lay terminology.[1]

1. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-non-invasive-remote-monitoring-devices-used-support-patient-monitoring-during

This announcement was authorised for release by the Board of Directors.

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About G Medical Innovations

G Medical **(ASX: GMV)** was founded in August 2014, aiming to be at the forefront of the digital health revolution, developing the next generation of mobile health (mHealth) technologies. The Company leverages the experience and expertise of its Board to deliver best-in-class solutions to address this global opportunity.

The Company specialises in innovative next generation mobile and e-health solutions using its suite of proprietary devices and software solutions, as well as patient service operations, with a view to driving multiple and recurring revenue streams, across numerous verticals and territories.

For more information on G Medical, please visit www.gmedinnovations.com

About G Medical products:

G Medical offers a suite of consumer and professional clinical-grade products (with regulatory approval) that are positioned to streamline healthcare services, improve remote access to medical data, reduce costs, improve quality of care, and make healthcare more personalized and precise. Currently the Company is focusing on two main verticals.

The 'Prizma' Medical Smartphone Case is one of two key products developed by G Medical and is aimed at everyday consumers focused on their medical health and wellbeing. The 'Prizma' allows consumers to turn their smartphone into a mobile medical monitor to measure a wide range of vital signs, with the added advantage that users are able to store their medical data in the cloud and share it with third parties such as healthcare professionals and family members.

G Medical also offers a professional real-time patient continuous monitoring solution, G Medical's Vital Signs Monitoring System (VSMS) and G Medical Patch (GMP). This modular solution measures a wide range of vital signs that are automatically presented in a call centre (IDTF) or a hospital setting. The GMP assists in diagnosing patient complaints and conditions remotely, from pre-hospitalisation, hospitalisation and through to post discharge home-based settings.