ASX ANNOUNCEMENT **18 November 2019**

HeraMED receives FDA 510(k) clearance for HeraBEAT device

- **HeraMED has received 510(k) clearance from the US Food and Drug Administration (FDA) for the HeraBEAT US (United States) foetal ultrasonic heart rate monitor**

- **HeraMED enabled to progress USA market entry**

- **HeraMED to leverage in-country relationship with existing partners to drive product uptake**

Medical technology company, **HeraMED Limited (ASX:HMD)** (**HeraMED** or the **Company**) is pleased to announce that its 510(k) application (reference number K191110) for the Company's HeraBEAT US foetal ultrasonic heart rate monitor (**HeraBEAT US**) has been cleared by the US Food and Drug Administration (**FDA**).

As elaborated in the FDA's 510(k) summary:

- **Intended use -** HeraBEAT US is intended to detect foetal heart beats, display foetal heart rate, and play the foetal heart sound. HeraBEAT US is indicated for use by medical professionals in clinical or home care settings for singleton pregnancies from 12 weeks gestation;

- **Device Description -** HeraBEAT US is a hand-held, battery powered audio Doppler device integrated with 2MHz probe, used for detecting and displaying the foetal heart rate (**FHR**) and FHR sound. The device uses an optical sensor to distinguish between the FHR and the maternal heart rate (MHR) to eliminate "crosstalk" in the FHR display.

HeraBEAT US includes the following components:

- The handheld HeraBEAT US device that incorporates an ultrasound transducer, rechargeable battery, and internal microcontroller and Bluetooth Low Energy (**BLE**) chip for wireless data transfer from the HeraBEAT US device to the user's smartphone.

- The HeraBEAT US application, which is downloaded from an app store to the user's smartphone. The HeraBEAT US application is used to communicate with the HeraBEAT US device using wireless BLE. It controls the operation of the device and receives the FHR values for numerical display to the user. It plays the FHR sound and stores the FHR values in a history log.

The FDA evaluates a wide range of items for medical use, including drugs and medical devices. The premarket review process for the HeraBEAT US device commenced in late April 2019 (refer to ASX announcement: 29 April 2019) and included rigorous review by FDA of HeraMED's comprehensive testing of the HeraBEAT US device. Receiving the 510(k) clearance for the HeraBEAT US device now allows that product to be commercially distributed throughout the United States. HeraMED will progress the device's entry into the US market, as quickly as practicable. To expedite this process, HeraMED will liaise with its current clinical and research and development collaborator the Mayo Clinic, as well as other medical institutions, hospitals and medical professionals to drive growth and product uptake.

The United States represents a potentially large and addressable market for the HeraBEAT US device, in which approximately four million pregnancies occur annually. HeraMED is confident that the HeraMED device will be well received in that market.

CEO and Cofounder Mr. David Groberman said: "Receiving FDA 510(k) clearance for the HeraBEAT US device is a tremendous achievement for HeraMED. The device development and testing, providing substantial evidence of the safety and effectiveness of the device, has passed a challenging and rigorous period of review by FDA and is now ready for distribution throughout the United States in the coming months. It will liaise with its in country partners, to ensure that process is as streamlined as possible."

-ENDS-

HeraMED Limited

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About HeraMED Limited (ASX:HMD):

HeraMED is an innovative medical Data and Technology company leading the digital transformation of prenatal care. HeraMED utilises the digital health ecosystem including clinical home monitoring devices, cloud computing, artificial intelligence, big data and digital social networking to reshape the Doctor/Patient relationship. The company is revolutionizing the pregnancy experience by empowering personalized, continuous and proactive home monitoring, to deliver better care at a lower cost. Keeping pregnant mothers engaged, informed and well-supported provides reassurance and peace of mind while allowing the healthcare providers to work at their highest levels of ability and enabling early detection of potential risks.