

US FDA 510(K) SUBMISSION FOR ROVER MOBILE MEDICAL X-RAY FOR MILITARY

Subject to regulatory clearance, Rover will be Micro-X's second commercial product for use in the US market

Adelaide, Australia, 10th June 2020: Australian hi-tech company Micro-X Ltd (ASX:MX1) (**Micro-X** or the **Company**), a leader in cold cathode x-ray technology for health and security markets globally, is pleased to announce the submission of a 510(k) application to the United States Food and Drug Administration (**FDA**) for its Rover mobile X-ray which is designed for deployed military medical facilities.

FDA 510(k) Pending

The 510(k) submission for the Rover was filed by Micro-X as manufacturer seeking approval for the sale of this device in the United States. The Centre for Devices and Radiological Health of the FDA has now provided the Company's regulatory advisers with an Acknowledgment Letter confirming receipt of a complete submission for the Rover and designating it with a tracking reference known as a K number.

The FDA has an established, 90-calendar day review timescale which commences with the submission of a 510(k) dossier. During this review period, FDA may request further or clarification information from the Company and the FDA may stop the process at any time depending on the nature of the review questions and the Company's ability to respond.

This regulatory filing marks an important step in commercialising the Company's second product, the Rover for deployed Military hospitals, in global markets. Once the FDA 510(k) approval for the Rover has been obtained, Micro-X will have achieved its first military product and then have two mobile X-ray products commercially available. Rover commercialisation is planned to be conducted through the Company's direct sales channel which will allow for greater control of the sales processes and superior product revenues and margins by not using distributors. US Department of Defense procurements require a 510(k) accreditation prior to contracting.

The Company plans to also seek CE Mark and TGA registration within the next 12 months to enable commercial access to the European Union and Australia.

Micro-X's Managing Director, Peter Rowland, commented:

"We are very pleased to have submitted Micro-X's first 510(k) application under its own name to the FDA. Obtaining FDA regulatory clearance is a key milestone of ours in 2020 as we are planning and building towards the launch of the Rover as our second commercial product later this year."

This ASX Announcement is authorised by the Board of Micro-X

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About Micro-X

Micro-X Limited (the **Company**) is an ASX listed hi-tech company developing and commercialising a range of innovative products for global health and security markets, based on proprietary cold cathode, carbon nanotube emitter technology. The electronic control of emitters with this technology enables X-ray products with significant reduction in size, weight and power requirements, enabling greater mobility and ease of use in existing x-ray markets and a range of new and unique security and defence applications. The Company has its core R&D, engineering and production capability at its facility in Adelaide, Australia.

The Company's first product, marketed as the *Carestream DRX Revolution Nano*, is an ultra-lightweight digital medical X-ray system for the rapidly expanding mobile X-ray market in hospitals and healthcare. The *Nano* holds 510(k) and CE Mark certifications and is sold commercially in a number of global markets by the Company's exclusive distributor. The second product, the Rover mobile X-ray for deployed military medical facilities, is

planned to be commercially launched in 2020 and an FDA 510(k) submission has been made to gain clearance for sale in the U.S. The Company has a portfolio of innovative products in development, aimed at customer solutions where there is little or no competition. This includes the Mobile Backscatter Imager or MBI which will image Improvised Explosive Devices for airport security, defence and counter-terrorism applications. The MBI is being jointly developed in partnership with Thales, a global supplier of defence and security technology systems, who are providing technical support and \$10 million of funding.

CONTACTS

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