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Wednesday 15th March 2017

ASX Announcement – MICRO-X LIMITED (ASX: MX1)

Nano Commercialisation Update: 'K' number received from FDA for Nano

Micro-X Limited (ASX: MX1) is pleased to advise that its distribution partner, Carestream Health Inc., has received from the US Food and Drug Administration (FDA) the 'K' number for the DRX Revolution Nano. This confirms that a valid 510(k) submission has been received by the FDA and the formal Acceptance Review has commenced.

Carestream has an extremely rigorous internal review process for 510(k) submissions which historically has been proven to minimise FDA approval times. FDA recently provided advice that the content of Premarket Submissions for the management of cybersecurity vulnerabilities in networked medical devices would be subject to increased scrutiny and additional work was necessary to strengthen the Nano's submission in this area.

The completion of the body of work for this submission marks a very significant milestone for Micro-X as it means that the Nano has satisfied all the rigorous design, safety and performance criteria for medical devices.

Carestream also lodged last week an application for a Medical Device Licence for the DRX Revolution Nano with the Therapeutic Products Directorate of Health Canada with a view to conducting Trade Trials in a Canadian hospital once the licence is issued.

Micro-X's intensive Reliability Growth Testing program for the Nano at Tonsley last week achieved the reliability target set. The Company has now decided to extend the testing program to further boost confidence in the durability of the unit as a competitive market discriminator.

For further information please contact:

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About Micro-X: Micro-X Limited ("MX1") is an Australian Securities Exchange listed company developing and commercialising a range of highly innovative products based on proprietary carbon nanotube emitter technologies exclusively licensed and sourced from XinRay Systems Inc., a US based technology developer. These technologies enable the miniaturisation of a number of X-ray applications relevant to large global markets.