



1 October 2021

Companies Announcement Office
ASX Limited
Exchange Centre
Level 4, 20 Bridge Street
Sydney, NSW 2000

Dear Sir/Madam

**INVESTEE CORTICAL DYNAMICS LIMITED FILES A 510(K) SUBMISSION WITH
THE FDA IN THE USA**

Investee Cortical Dynamics Limited is pleased to announce that it has filed a 510(K) submission with the FDA in the USA for its medical device, the Brain Anaesthesia Response Monitor (BARM™).

BARM™ takes a physiological approach to measuring the effects of anaesthetic drugs on brain electrical activity for surgical operations under General anaesthetic. The BARM™ algorithm is derived from a model of how human EEG (electrical activity of the brain) is generated. BARM™ describes the electrical activity of populations of excitatory and inhibitory neurons within the cerebral cortex, and uses established physiological parameters such as the number of connections between neuronal populations, conduction velocities, and firing rates and thresholds. The model can produce the main features of spontaneous human EEG and the effects general anaesthetics have on the EEG providing anaesthetists with valuable feedback as to the depth of anaesthesia experienced by patients.

Cortical Dynamics Limited was assisted in the FDA submission by MCRA, the leading U.S. Regulatory Advisor for the Medical Device and Biologics industries.

BARM™ is already CE, TGA and Korea MFDS regulated.

Authorised for release by

David Breeze
Executive Director