

ElectroCore GammaCore therapy gets Aus TGA nod

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Singapore: ElectroCore's GammaCore therapy has been approved for commercial sale by the Therapeutic Goods Administration (TGA) in Australia and by the National Institute of Surveillance of Medicine and Foods in the Ministry of Health in Colombia.

GammaCore's non-invasive, non-pharmaceutical, neuromodulation therapy is indicated for the acute and prophylactic treatment of primary headache (migraine, cluster headache and Hemicrania Continua) and medication overuse headache in adults.

GammaCore is currently available to patients in Australia, who are under the care of a physician, and can be ordered through ElectroCore Australia. ElectroCore plans to make the device available in Colombia in the first half of 2013.

"These approvals represent significant additional regulatory validation of the GammaCore technology as a safe and effective therapy," said Mr J P Errico, CEO of ElectroCore. "These approvals are great news for patients in Australia and Colombia who suffer from primary headache, as they provide another non-invasive treatment option."

ElectroCore recently received US FDA approval to begin its pivotal study of GammaCore as an acute treatment for cluster headaches. This trial, expected to begin enrolling during the first quarter of 2013, will study the acute benefits of treatment of cluster headache events in 150 subjects at fifteen sites across the US-based on the results of the study, ElectroCore plans to submit a Pre Market Approval (PMA) for FDA approval of GammaCore for the acute treatment of cluster headaches. GammaCore is not currently available for sale in the US.