CircuLite, NeuroSigma land CE Marks

Mass Device

CircuLite won CE Mark approval in the European Union for its Synergy heart pump; EuroZone regulators also OK NeuroSigma's Monarch trigeminal nerve stimulation device for epilepsy and depression.

The European Union granted CE Mark approval to a pair of medical device companies, CircuLite and NeuroSigma, for their technologies designed to treat heart failure, epilepsy and depression.

Middle Brook, N.J. and Aachen, Germany-based CircuLite said it landed its EuroZone nod for its Synergy heart pump, designed to treat ambulatory heart disease patients. The battery-sized device is inserted into a subcutaneous pocket under the right collarbone, unlike the left ventricular assist devices it competes with, which require open heart surgery. Thoratec [1] (NSDQ:THOR [2]) and HeartWare International [3] (NSDQ:HTWR [4]) are the leading LVAD manufacturers.

"With CE Marking in place, we will begin a controlled launch of this ground-breaking advancement in select European markets," president and CEO Paul Southworth said in prepared remarks [5].

Links:
[1] http://www.massdevice.com/company/thoratec-corp
[2] http://www.google.com/finance?q=thor
[3] http://www.massdevice.com/company/heartware-international-inc
[4] http://www.google.com/finance?q=htwr
[5] http://www.businesswire.com/news/home/20120905005653/en/CircuLite%C2%AE-Receives-CE-Marking-Approval-SYNERGY%C2%AE-Circulatory