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Number To Know...3

by

Only three leadless pacemakers have been CE marked to date, as revealed following the publication of recent UK guidelines on how to evaluate such products.

There are only three leadless cardiac pacemakers that have received a CE-mark to date, according to a recent guideline issued by the UK Medicines and Healthcare products Regulatory Agency on the clinical evaluation of such products. At the time of writing the March 2017 [guideline](#), the MHRA said CE-marks had been awarded to [St. Jude Medical Inc.](#) 's *Nanostim* and [Medtronic PLC](#) 's *Micra* – both of which are intracardiac, entirely self-contained rate-responsive ventricular demand (VVIR) pacemakers. Also, CE-mark had been granted to [EBR Systems Inc.](#) ' *WICS*, which effectively adds CRT (cardiac resynchronization therapy) capability to an existing transvenous Implanted pacemaker/implantable cardioverter defibrillator. Other leadless pacing systems are in development and it is thought that this modality may one day provide a wider range of therapies, including multisite endo- or epicardial pacing for CRT plus antitachycardia pacing in combination with non-transvenous ICDs.

To gain more insight on MHRA's guideline on this topic, read *Medtech Insight's* article [here](#).