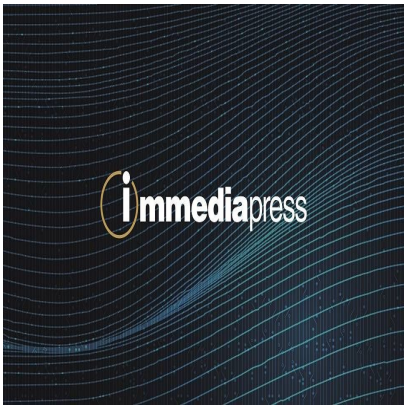

Valgen Medtechâ??s DragonFlyâ?¢ System Receives EU Approval for FMR Indication

Descrizione

COMUNICATO STAMPA â?? CONTENUTO PROMOZIONALE

FRANKFURT, Germany and HANGZHOU, China, June 24, 2026 /PRNewswire/ â?? Valgen Medtech recently announced that its proprietary DragonFlyâ?¢ Transcatheter Mitral Valve Repair System has received CE mark approval in the European Union for the treatment of Functional Mitral Regurgitation (FMR).

Following its EU approval for Degenerative Mitral Regurgitation (DMR) in April 2025, this latest authorization positions the DragonFlyâ?¢ System as the first transcatheter mitral valve repair device originating in China to receive EU approval for both DMR and FMR indications.

Evolving International Clinical Guidelines and Consensus

Mitral regurgitation (MR) is one of the most prevalent valvular heart diseases worldwide. FMR, which commonly occurs in patients with heart failure, remains a particularly complex condition to manage in clinical practice. In recent years, a growing international consensus has emerged regarding optimal treatment strategies for this condition:

Robust Global Clinical Evidence

The DragonFlyâ?¢ System is supported by an extensive body of clinical evidence generated through a series of multicenter studies across Asia, Europe, and other international regions, including the DragonFly-DMR, DragonFly-FMR, and DragonFly-EU pivotal trials. One-year follow-up results from the DragonFlyâ??DMR EU Pivotal Study, presented by Valgen Medtech at CSI Frankfurt 2026, demonstrated favorable safety, durability, and clinical performance in elderly patients with severe DMR who were at high surgical risk:

To date, DragonFlyâ?¢ has received regulatory approvals in 15 countries and regions, with routine clinical use and commercial adoption already underway in key international markets including Latin America and Southeast Asia. Valgen Medtech remains committed to innovation driven by clinical needs, expanding access to safe, effective, and minimally invasive treatment options for patients worldwide.

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