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Concept Medical receives 3rd IDE approval from USFDA for MagicTouch-Sirolimus Coated Balloon

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For the treatment of small vessel indication in coronary arteries



Surat-based Concept Medical Inc. (CMI), with presence in The Netherlands, US, Singapore and Brazil, has received its third Investigational Device Exemption (IDE) approval from the US Food and Drug Administration (FDA) for its novel Sirolimus-Coated Balloon, Magic Touch SCB, for the treatment of Small Vessels (SV) in Coronary Arteries.

This milestone comes after CMI received IDE approvals for Magic Touch SCB to treat Coronary In-Stent Restenosis (ISR) in September 2022 and Magic Touch PTA to treat "Below the Knee" Peripheral Arterial Diseases (PAD) in February 2022.

The IDE approval allows Concept Medical to conduct pivotal clinical studies to gather safety and effectiveness data for the Magic Touch Sirolimus Coated Balloon in small vessel coronary disease. This data will support a future pre-market approval (PMA) application in the USA, providing patients and physicians with an alternate product for the treatment of Coronary Artery Disease (CAD).

Currently, there are no FDA approved Drug Coated Balloons for the treatment of CAD in the USA, and the patients are limited to the availability of Drug Eluting Stents and uncoated Balloons. MagicTouch has already been widely studied globally in multiple clinical trials, most notably the EASTBOURNE Registry (2123 patients), NANOLUTE, and ongoing trials like the TRANSFORM 1, TRANSFORM 2, GINGER, TITAN, and Hybrid Bifurcation DEB. Sirolimus has already proven to be safer in coronary artery disease treatment.

Notably, no Indian company has received IDE approval for a Drug-Coated Balloon in the USA, either in the Peripheral or Coronary indications. This achievement has the potential to be a game changer for the healthcare industry, healthcare professionals, and patients at large, providing an alternate product for the treatment CAD & PAD.