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FDA grants 'Breakthrough Device Designation' to Concept Medical

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Concept Medical Inc. (CMI) has been granted "Breakthrough Device Designation" from the U.S. Food and Drug Administration (FDA) for MagicTouch, its Sirolimus drug-coated balloon (DCB) catheter, for the treatment of coronary in-stent restenosis (ISR).

In-stent restenosis (ISR) is the gradual re-narrowing of a stented coronary artery lesion, due to subsequent tissue proliferation at the stented site. ISR is observed in about 10 percent of patients who undergo a drug eluting stent (DES) implantation and in more than 30 percent of patients who undergo bare-metal stent (BMS) implantation. Such patients, who come back with re-clogging of the coronary arteries following an earlier procedure of a bare metal or a drug-eluting stent implant, are candidates for treatment with the MagicTouch.

The goal of the FDA "Breakthrough Devices Program" is to provide patients and health-care providers in the U.S. with timely access to these medical devices by speeding up their development, assessment and review, while preserving the statutory standards for premarket approval, 510(k) clearance and De Novo marketing authorization, consistent with the agency's mission to protect and promote public health.

The Breakthrough Devices Program offers manufacturers an opportunity to interact with the FDA's experts through several different program options to efficiently address topics as they arise during the premarket review phase, which can help manufacturers receive feedback from the FDA and identify areas of agreement in a timely way. Manufacturers can also expect prioritized review of their submission. Under the program, FDA will provide CMI with priority review and interactive communication regarding device development and clinical trial protocols, through to commercialization decisions.

"The FDA's designation of MagicTouch for the Breakthrough Device Program will allow CMI to meet its ambition to provide this promising technology and innovative treatment for ISR patients in the USA. Our confidence in MagicTouch emanates

from the positive feedback that we are receiving from the users of our product from current and ongoing commercial sales of MagicTouch in many European countries," said cardiologist Dr. Kiran Patel, chairman of CMI. "CMI is encouraged that the selection of MagicTouch, with its unique drug delivery technology, for the FDA's Breakthrough Device Program may allow timely access of this promising new technology to the U.S. patients with coronary ISR, with a potential to provide safe and effective treatment."