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Peijia Medical Limited

沛嘉醫療有限公司

(Incorporated in the Cayman Islands with limited liability)

(Stock Code: 9996)

VOLUNTARY ANNOUNCEMENT

SUBMISSION OF EU MDR CE MARK REGISTRATION FOR THE GeminiOne® TRANSCATHETER EDGE-TO-EDGE REPAIR SYSTEM

This announcement is made by Peijia Medical Limited (the “**Company**”, together with its subsidiaries, the “**Group**”) on a voluntary basis to provide the shareholders of the Company and potential investors with updated information in relation to the latest business and new product development progress of the Group.

The board (the “**Board**”) of directors (the “**Directors**”) of the Company is pleased to announce that the Company has recently formally submitted the EU MDR CE Mark registration application for the GeminiOne® Transcatheter Edge-to-Edge Repair (“**TEER**”) System (the “**System**”) for the treatment of mitral regurgitation, with HighLife SAS being the European partner. The submission of the CE Mark registration application signifies the Company’s steady progress in advancing its globalization strategy.

GeminiOne® is a novel TEER device internally developed by the Company. Its unique sliding groove mechanism enables a longer coaptation length, along with a smaller implant size and delivery system. Additional innovations include an independent leaflet grasp that reduces procedural complexity, an auto-locking mechanism that prevents repeated locking and unlocking during the procedure, and a multi-angular detachment that accommodates a wider range of anatomy. The design of the System has been patented globally and obtained clearance through multiple freedom-to-operate analyses.

As at the date of this announcement, the registration application for GeminiOne® has been accepted by the National Medical Products Administration of the People's Republic of China and is currently under review. In addition, GeminiOne® has obtained Investigational Device Exemption approval from the U.S. Food and Drug Administration for an Early Feasibility Study. The Company will actively advance the registration of the product in China and Europe, with the aim of bringing safe and effective treatment options to patients with mitral regurgitation at the earliest practicable opportunities.

THE COMPANY MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET GeminiOne® TEER SYSTEM SUCCESSFULLY. SHAREHOLDERS OF THE COMPANY AND POTENTIAL INVESTORS ARE ADVISED TO EXERCISE DUE CARE WHEN DEALING IN THE SHARES OF THE COMPANY.

By order of the Board
Peijia Medical Limited
Dr. Yi ZHANG
Chairman and Executive Director

Hong Kong, February 9, 2026

As of the date of this announcement, the Board comprises Dr. Yi ZHANG, Mrs. Ping Ye ZHANG and Ms. Hong YE as executive Directors, Mr. Jifeng GUAN, Mr. Fei CHEN, Mr. Jun YANG as non-executive Directors, and Dr. Stephen Newman OESTERLE, Mr. Robert Ralph PARKS, Mr. Wai Ming YIP, Mr. Huacheng WEI as independent non-executive Directors.