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Edwards gets SFDA nod for heart valve

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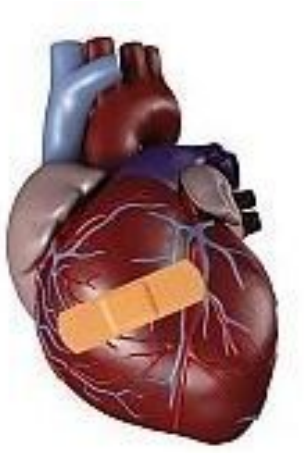

Singapore: Edwards Lifesciences, the global leader in the science of heart valves and hemodynamic monitoring, received approval from China's State Food and Drug Administration (SFDA) for its Carpentier-Edwards Perimount Mitral Heart Valve, a replacement heart valve made of bovine pericardial tissue.

"The Perimount Mitral Heart Valve provides an important therapeutic option for mitral valve replacement, particularly for those patients with lifestyle considerations that may not be compatible with the lifelong blood-thinning medication required with mechanical heart valves," said Mr Shengshou Hu, resident of Fuwai Hospital and China National Heart Center. "This valve offers excellent hemodynamics and established long-term durability, providing Chinese surgeons with an important new, yet clinically established, treatment for their patients suffering from mitral valve disease."

Designed for the treatment of mitral valve disease, the Perimount Mitral Heart Valve was introduced into clinical use in 1984 and has demonstrated long-term endurance, as reported in numerous peer-reviewed studies. The valve is treated with the Carpentier-Edwards ThermaFix process, the only anti-calcification tissue treatment that targets both major calcium binding sites that lead to tissue calcification. Edwards' family of Perimount pericardial valves have been the world's most frequently implanted valves for more than 30 years.

"The approval in China of our market-leading Perimount Mitral Heart Valve represents a clinically significant advancement for patients in the country suffering from mitral heart valve disease," said Mr Donald E Bobo, Edwards' corporate vice president, heart valve therapy. "We are committed to bringing life-saving therapies that treat heart valve disease to Chinese surgeons and their patients."

The Carpentier-Edwards Perimount Mitral Heart Valve was approved for US commercial distribution in 2000 and bears the CE mark for countries in the European Union.