Medtronic Receives FDA Approval Non-Surgical Heart Valve

Medtronic recently announced that its Melody® Transcatheter Pulmonary Valve has received U.S. Food and Drug Administration approval under a Humanitarian Device Exemption. It is the first transcatheter heart valve to receive FDA approval.

Delivered through a catheter requiring only a small incision, the Melody valve will benefit children and adults who are born with a malformation of their pulmonary valve, which is the valve between the heart and lungs. These patients often require open-heart surgery to restore effective blood flow to their lungs. Previously, the only way to repair or replace a failed pulmonary valve conduit was through additional surgeries.

In October 2006, the Melody valve became the first transcatheter valve to receive regulatory approval anywhere in the world when it received the CE (Conformité Européenne) mark. HDE is a special regulatory approval for treatments intended for fewer than 4,000 U.S. patients per year. HDEs are granted for medical devices that have demonstrated reasonable safety and probable benefit, but not clinical effectiveness.