

Trial Demonstrates Potential Benefits of Medtronic Pulmonary Valve

The first-of-its kind device is currently under review by the U.S. Food and Drug Administration (FDA) for approval of a humanitarian device exemption (HDE), based on evidence of safety and probable benefit for the Melody valve. On July 22, an FDA advisory panel voted unanimously to recommend conditional approval of the Melody valve, but the device remains investigational in the United States until FDA makes a final decision.

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