FDA approves expanded indication for CRT devices

April 15 2014

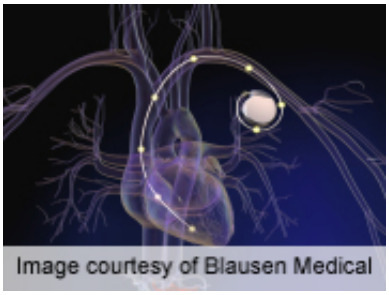

Image courtesy of Blausen Medical

(HealthDay)—The U.S. Food and Drug Administration has approved an application from Medtronic for revised labeling for two cardiac resynchronization pacemakers (CRT-P) and eight cardiac resynchronization defibrillators (CRT-D). The approval expands the indication for use to patients with atrioventricular block and less severe heart failure, according to a press announcement issued by the FDA.

The FDA had previously approved these devices for patients with more severe heart failure. This new approval includes use among patients with less severe heart failure but who are already indicated to receive right ventricle pacing. These patients will now be eligible to receive a device that will pace both sides of their heart instead of just the right.

The expanded approval for the CRT-D and CDT-P devices was based on

data from the Block HF clinical study that compared death, heart failure-related urgent care visits, and increases in left ventricular end systolic volume index (LVESVI). A total of 918 subjects participated in the trial; 531 received a CRT-P device and 227 received a CRT-D device. The cardiac resynchronization therapy provided by CRT-P and CRT-D devices demonstrated a 27 percent reduction in death, heart-failure-related urgent-care visits, and increases in LVESVI compared to right ventricular pacing alone.

"Medtronic's cardiac resynchronization therapy pacemakers and defibrillators can delay the occurrence of heart failure-related urgent care visits for people who meet these new criteria," Christy Foreman, director of the Office of Device Evaluation in the FDA's Center for Devices and Radiological Health, said in a statement. "This approval expands the indication of cardiac resynchronization therapy to this additional patient population."

More information: More Information