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The FDA's Circulatory Systems Device Panel this week voted in favor of Impulse Dynamics's Optimizer Smart implantable pulse generator, supporting the company's premarket approval application seeking clearance for use in patients suffering from heart failure, according to a *Healio* report.

The Optimizer impulse generator is designed to remodel the myocardium to increase the heart's efficiency using what the company calls the cardiac contractility modulation – non-excitatory electrical pulses delivered to the heart muscle. The system has had CE Mark approval in the European Union for the device since 2002.

The FDA's Circulatory Systems Device Panel voted 12 to 1 in favor of the device's safety and 11 to 2 in favor of its efficacy, according to *Healio*. The panel also voted 12 to 0, with a single abstention, that benefits of the device outweighed the risks.

The device came supported by safety and efficacy evidence from the 418-patient FIX-HF-5 study of the device, which compared treatment with CCM to guideline-directed medical therapy for heart failure patients, according to the report.

The trial's primary safety endpoint was defined as a composite event rate of all-cause hospitalizations and all-cause mortality through 50 weeks, which was reported at 4.9% in the CCM treatment arm and 3.3% in the control arm, according to *Healio*. No deaths were reported as caused by the implant procedure or the device, and rates of events that required invasive treatment or hospitalization were balanced between groups.

The primary effectiveness endpoint of the trial, defined as the difference in responder rates between the CCM and control groups, was reported at 5.9%, with a 17.6% rate in the CCM arm and 11.7% in the control group. The difference was not reported as being statistically significant.

The system was also supported by data from the 160-patient FIX-HF-5C study which had a similar patient population to the FIX-HF-5 study, according to *Healio*.

The primary safety endpoint in the second trial was defined as the percentage of CCM patients who experienced either device- or procedure-related complications through 24 weeks. Results indicated that 90% of CCM patients were free from complications at follow-up, according to the report.

The primary effectiveness endpoint in the trial was the mean difference in peak VO2 between the CCM and control arms at 24 weeks. Investigators included data from nearly 30% of patients from the FIX-HF-5C study for assessing the endpoint, *Healio* reports. With imputation of zeroes performed to account for six deaths, peak VO2 was 14.21 ml/kg/min for the control arm vs 15.04 ml/kg/min for the CCM arm, from baseline VO2 levels of 15.4 ml/kg/min.

A registry for a post-approval study was proposed that will seek to collect data from 300 patients for two years, with a similar format to left atrial appendage occlusion and transcatheter aortic valve replacement registries, according to the report. Investigators in the study plan to review all-cause mortality and 1- and 2-year mortality assessments as compared with the Seattle Heart Failure Model scoring system.

The company won a date with an FDA panel in October. Last May, Impulse Dynamics said that it closed a $45 million equity financing round to support its CCM tech.

The post FDA panel votes in support of Impulse Dynamic's cardiac contractility modulation pulse generator appeared first on MassDevice.