Submission Asset Upload — *Abstract Section*

Company name: Impulse Dynamics

Company logo: A picture containing font, text, graphics, screenshot

Description automatically generated

Product name: Optimizer® Smart Mini System

Compound name: Optimizer® Smart Mini

Date of FDA approval: 07/30/2021

Indications: The Optimizer® Smart is the first and only CCM device approved by the FDA to improve a 6-minute hall walk distance, quality of life, and the functional status of NYHA Class III heart failure patients who remain symptomatic despite guideline-directed medical therapy, in normal sinus rhythm, not indicated for CRT, and have an LVEF ranging from 25% to 45%.

Drug innovation description: Impulse Dynamics is a fast-growing medical device company that has pioneered a new form of therapy for heart failure called cardiac contractility modulation. This treatment, provided by the company’s Optimizer® Smart Mini System, which delivers ***CCM***®therapy, is an FDA-approved device. CCM is a ﬁrst-of-a-kind, proprietary, life-changing treatment alternative for a vast population of heart failure patients worldwide. We are driven by an unwavering commitment to signiﬁcantly improve heart failure patients’ lives by transforming how their condition is treated.  
  
CCM therapy is delivered by the Optimizer, a minimally invasive, implantable device. The innovative treatment is designed to improve the contraction of the heart, allowing more oxygen-rich blood to reach the body. Studies evaluating the FDA-approved therapy have demonstrated the device is safe and is proven to improve the quality of life for suitable patients. CCM therapy may be an appropriate treatment option for approximately 70 percent of NYHA Class III heart failure patients who remain symptomatic despite guideline-directed medical therapy.  
  
CCM therapy delivers precisely timed electrical pulses to the heart during the absolute refractory period of the beating cycle, just after the heart contracts. The approach was proven safe and eﬀective in numerous clinical studies, including several randomized controlled trials. The results have been published in over 120 articles appearing in leading medical journals. The Optimizer has been used to treat over 9,000 patients. It is available in the United States, Europe, China, Brazil, India, and more than 40 other countries worldwide.

Additional information: Website: <https://ImpulseDynamics.com>   
  
LinkedIn: <https://linkedin.com/company/impulse-dynamics>   
  
Twitter: @ModulateHF  
  
Facebook: <https://www.facebook.com/ModulateHF>   
  
Instagram: ImpulseDynamics   
  
YouTube: <https://youtube.com/@CCM_for_HF>