

Optimizer® Smart Mini System

Category:

Best Medical Technology

Company Name:

Impulse Dynamics

Product/Solution Name:

Optimizer® Smart Mini System

Compound/Tech Name:

Optimizer® Smart Mini

Trade Name:

Optimizer® Smart Mini

Corporate Name:

Impulse Dynamics

Date of Approval:

2021-07-30

Indications:

The OPTIMIZER Smart Mini System, which delivers CCM™ therapy, is indicated to improve 6-minute hall walk, quality of life, and functional status of NYHA Class III heart failure patients who remain symptomatic despite guideline directed medical therapy, are not receiving Cardiac Resynchronization Therapy (CRT), and have a left ventricular ejection fraction ranging from 25% to 45%.

Therapeutic Areas:

Heart Failure

General Information File Document upload:

N/A

Background information and need for drug / device:

Heart failure affects an estimated 6.5 million Americans and nearly over 64 million people worldwide.

By 2030, over 8 million people in the United States - one in every 33 - will have HF.

Heart failure is a condition in which the heart slowly weakens and cannot pump with force required to supply oxygen-rich blood to meet the body's needs.

Patients with heart failure experience debilitating symptoms, including breathlessness, fatigue, confusion, and swelling in the legs that make everyday activities challenging and significantly diminish their quality of life.

Traditional treatments for heart failure provide limited or no, improvement to the heart's pumping forcefulness, and nearly 50 percent of people with heart failure die within five years of being diagnosed.

Today, most heart failure patients are prescribed medications intended to slow the progression of the disease and manage their symptoms.

As the condition progresses, these treatments lose their effectiveness, and the quality of life for heart failure patients will continue to decline.

The total annual cost for heart failure is projected to reach \$70 billion by 2030.

Background File Document upload:

[Impulse Dynamics Optimizer Background Information and Need for Device.docx](#)

History of the development of the solution/product:

History of the Development of the Optimizer® Smart Mini Device (below)

1999: Impetus I

The Impetus I. was the first implantable CCM device, which included a fully functional DDD pacemaker and a dedicated CCM output called ETC (excitable tissue control).

2000: Impetus II

The Impetus II. Was the first CCM device to utilize a local-sense-based delivery

algorithm - CCM signals could be adapted to activity levels using an onboard accelerometer.

2001: Optimizer I

The Optimizer I. was the first device to test CCM delivery to the RV in human subjects.

2001: Optimizer II

The Optimizer II. was the first CCM device to provide therapy on an automated daily schedule, RA and RV sensitivity ranges were extended with CCM delivered through RV and LS leads.

2004: Optimizer III

The Optimizer III. was the first-ever Li-ion cardiac IPC - the header was reconfigured to deliver CCM therapy to the RV. Over nine years of clinical data were collected using this device.

2013: Optimizer IVs

The Optimizer IVs featured an inductive charging coil that was reduced in size and moved to the header. The advanced hardware platform resulted in a dramatic volume reduction.

2016: Optimizer® Smart System

The Optimizer® Smart System was FDA-approved in 2019 and awarded the FDA designation as a \"Breakthrough\" device. This device only required two RV leads and was MRI-conditional.

2022: Optimizer® Smart Mini System

Today's current Optimizer® device generation is our latest CCM therapy delivery system. The Optimizer® Smart Mini is 25% smaller and 33% lighter than the previous Optimizer® Smart model introduced in 2016. This model is designed as a physiologically shaped implantable enclosure with a 20-year battery life and provides RF telemetry and advanced diagnostic monitoring.

Development File Document upload:

[Impulse Dynamics Optimizer History of the Development of the Optimizer Smart Mini Device.docx](#)

Why this drug or device is innovative, the broad implications for future research, and/or how it will improve the human condition:

In the landscape of heart failure, patients are defined by their symptoms. Each class of heart failure is marked by a progression of debilitating and constricting symptoms.

Patients are waiting to feel bad enough for intervention, for change, for help. CCM® therapy can change that.

IMPULSE DYNAMICS is a global medical device company that has pioneered a new form of heart failure (HF) therapy called cardiac contractility modulation. This treatment, provided by the company's Optimizer® Smart Mini System, delivers CCM® therapy to the heart to reduce HF symptoms. The treatment is indicated for HF patients having an LVEF ranging from 25 to 45% to enhance their quality of life by achieving the 6-minute hall walk and reducing HF symptoms, such as shortness of breath, fatigue, swelling, chest pain, and more. CCM® therapy is a proprietary, life-changing treatment option for a vast population of heart failure patients searching for new hope in improving their quality of life (QoL) by significantly reducing heart failure symptoms.

People with heart failure deserve more than waiting for their lives and bodies to deteriorate enough to get an LVAD or a transplant. The medical devices available to heart failure patients are life-saving. But, in a lot of cases, they are not life-changing. CCM® therapy is a revolutionary heart failure therapy that puts the patient's quality of life first. It offers patients a chance to participate in the life they are trying to save.

People's lives are made up of diverse interests, passions, connections, and dreams. Mary, a heart failure patient from Arizona, loves to play golf. She was a hairdresser and is a grandmother. She babysat her 5 grandchildren often, until her HF symptoms got too severe to continue. She couldn't play golf, and she couldn't work. She could barely walk a city block. Within a week of receiving CCM® therapy, she started to feel better.

Mary can spend time with her family. She can play golf, she can even walk the course, if she wants. She won two ladies golf tournaments since her implant. Her EF went from 25% to 45%. A majority of patients who receive CCM® therapy - 81% - improve by at least one HF class with CCM® therapy. Forty one percent improved by two NYHA HF classes. Mary isn't waiting to get worse, Mary is living her life, wholeheartedly.

Mary is one of over 10,000 patients who have been helped by CCM® therapy, whose life has dramatically improved. We are dedicated to making that impact on more patients. We want to change the standard of care for HF patients; shift the management of heart failure to include quality of life. HF patients deserve the ability to live their lives and enjoy their time, even with heart failure.

Innovation File Document upload:

[DOC Why is the Optimizer Smart Mini innovative.docx](#)

[DOC Why is the Optimizer Smart Mini innovative 20.docx](#)

[Impulse Dynamics Innovation Submission .docx](#)

Impulse Dynamics Innovation Submission .docx

Please provide appropriate references (PubMed, Abstract, Website):

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- [2] Benjamin EJ, Blaha MJ, Chiuve SE, et al. Heart disease and stroke statistics-2017 update: A report from the American Heart Association. *Circulation*. 2017;135(10). doi:10.1161/cir.0000000000000485
- [3] Abraham WT, Lindenfeld JA, Reddy VY, et al. A randomized controlled trial to evaluate the safety and efficacy of cardiac contractility modulation in patients with moderately reduced left ventricular ejection fraction and a narrow QRS duration: Study rationale and design. *Journal of Cardiac Failure*. 2015;21(1):16-23. doi:10.1016/j.cardfail.2014.09.011
- [4] Kuschyk J, Falk P, Demming T, et al. Long-term clinical experience with cardiac contractility modulation therapy delivered by the optimizer smart system. *European Journal of Heart Failure*. 2021.doi:10.1002/ejhf.2202
- [5] Abraham WT, Burkhoff D, Nademanee K, et al. A randomized controlled trial to evaluate the safety and efficacy of cardiac contractility modulation in patients with systolic heart failure: Rationale, design, and Baseline Patient Characteristics. *American Heart Journal*. 2008;156(4). doi:10.1016/j.ahj.2008.05.019

References File Document upload:

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