

Category

Best Medical Technology

Drug / Device Name

Optimizer® Smart Mini System

Compound/ Tech Name

Optimizer® Smart Mini

Trade Name

Optimizer® Smart Mini

Date of Approval

2021-07-30

Indications

The Optimizer® Smart Mini is the latest 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%.

Therapeutic Categories

Heart Failure

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.

Attached Files:

- DOC Background Information and Need for Device.docx

History of the development of the drug/device

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.

Attached Files:

- DOC 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

BACKGROUND

Impulse Dynamics is a fast-growing global medical device company that pioneered a new form of heart failure (HF) therapy called cardiac contractility modulation. This treatment, called CCM® therapy, is provided by the company's Optimizer® Smart Mini System — our latest CCM therapy delivery system. This device is 25% smaller and 11% lighter than the previous Optimizer® Smart introduced in 2016. The current model, which is FDA-approved, is designed as a physiologically shaped implantable enclosure with a 20-year battery life and provides RF telemetry and advanced diagnostic monitoring.

CCM THERAPY — A BREAKTHROUGH APPROACH

CCM therapy is delivered by the Optimizer® Smart Mini System, a minimally invasive, implantable device. The innovative treatment is the most recent generation designed to improve the contraction of the heart, allowing more oxygen-rich blood to reach the body.¹ Studies evaluating the FDA-approved therapy have demonstrated the device is safe and is proven to improve the quality of life for suitable patients.¹ The Optimizer Smart Mini delivers CCM® therapy, the company's proprietary technology, to the heart.¹

CCM therapy provides 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.²

The Optimizer® Smart Mini System is the latest CCM therapy delivery system that is FDA-approved (as of July 10, 2021) for treating heart failure patients in the United States. At the time of this submission, CCM therapy has been used to treat over 9,000 heart failure patients; it is currently available in the United States, Europe, China, Brazil, India, and more than 40 other countries worldwide.

CCM THERAPY — AN EFFECTIVE OPTION FOR MILLIONS OF HEART FAILURE PATIENTS

CCM therapy, delivered by the company's Optimizer® Smart Mini device, is an FDA-approved treatment proven to improve the quality of life for heart failure patients.¹ The therapy is a safe and effective minimally invasive treatment option for many heart failure patients who otherwise have few effective options available to them. Additionally, it's an innovation that can improve the lives of heart failure patients who continue to experience symptoms despite receiving medical therapy.¹

CCM therapy provides an option that improves the quality of life for patients who are no longer adequately responding to medications to manage symptoms or slow the progression of heart failure.¹ 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.¹

The treatment is indicated for heart failure patients having a left ventricular ejection fraction (LVEF) ranging from 25 to 45 percent to enhance their quality of life by achieving the 6-minute hall walk and reducing heart failure symptoms, such as shortness of breath, fatigue, swelling, chest pain, and more.

HOW THE DEVICE WORKS

The Optimizer® Smart Mini device is similar in size to a pacemaker and is implanted during a minimally invasive procedure while the patient is under light sedation. During the procedure, the device is implanted under the skin of the upper chest, along with electrical leads placed in the heart's right ventricle through the veins (transcatheter). After the procedure, the physician programs the delivery of CCM therapy for each patient and activates the device.

Following the programming of CCM therapy, the implanted device sends electrical pulses to the heart muscle for a total of five hours a day, in one-hour treatments separated by regular intervals. From the comfort of their home, the patient can charge the device weekly for one hour using an external charger. The Optimizer® Smart Mini System has been rigorously tested, and it is expected to provide CCM therapy for up to 20 years before requiring replacement.

REFERENCES

[1] 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):16-21. doi:10.1016/j.cardfail.2014.09.011

[2] 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*. 2

Attached Files:

- DOC Why is the Optimizer Smart Mini innovative.docx
- DOC Why is the Optimizer Smart Mini innovative 20.docx

Please provide appropriate references (ie Pubmed links)

[1] Groenewegen A, Rutten FH, Mosterd A, Hoes AW. Epidemiology of Heart Failure. *European Journal of Heart Failure*. 2020;22(8):1342-1356. doi:10.1002/ehf.1858

[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/ehf.2202

[5] Abraham WT, Burkhardt 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

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- DOC References.docx