

Lightengale Awarded FDA Safer Technologies Program (STeP) Designation for IVT System

New FDA Designation Facilitates a Fast-Track for Market Clearance

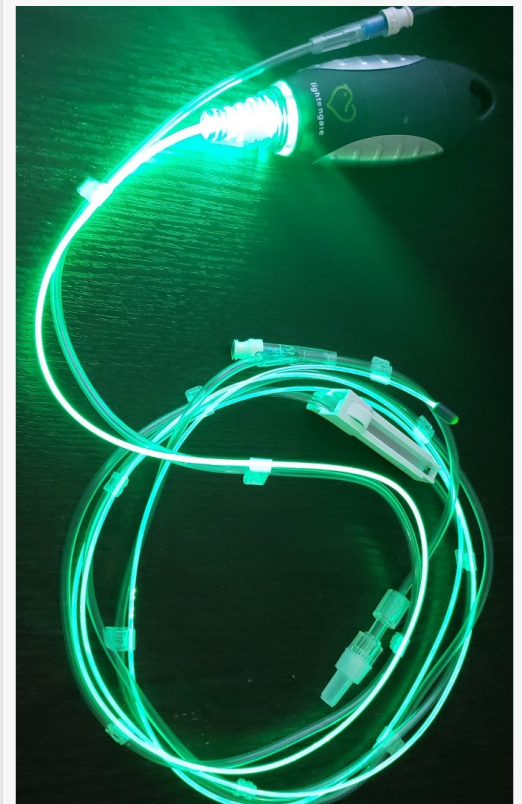
ATLANTA, GEORGIA, USA, February 13, 2023

/EINPresswire.com/ -- [Lightengale](#), an innovator in intravenous tubing (IVT) systems, announced that they received Safer Technologies Program (STeP) designation from the Food and Drug Administration (FDA) for their [illuminated IVT system](#). Awarded on October 28, 2022, Lightengale's illuminated IVT system was accepted with proposed indications for use for "the administration of fluids from a container into the patient's vascular system through a vascular access device." With STeP support, Lightengale will have access to key FDA resources, enabling them to quickly receive the feedback and support needed to bring their innovation to market safely and have a positive impact on overburdened ICUs.

The Lightengale illuminated IVT system was developed to overcome the challenges and complexity of the IVT tracing process to improve patient safety. Lightengale uses fiber optic and LED technology to illuminate IV lines on demand. By illuminating the entire length of the line, nurses can quickly and accurately identify IVT in the ICU. The system seamlessly integrates with current IVT tracing protocols.

IV-line mix-ups are one of the most frequent infusion line medication error events. To avoid error, the primary protocol is to physically trace the lines. IVT tracing is a complex and difficult process, with 7.7% of traces shown to end in line misidentification.¹ Lightengale's system aims to lessen the risks of IVT tracing and reduce the incidence of IV medication errors and related adverse events in ICUs.

"We are honored to receive our recent STeP designation for our IVT system, and excited about the opportunities and benefits this program offers. Through access and collaboration with FDA experts, we will be able to ultimately reduce the time to obtain our market clearance. We are



Lightengale Illuminated
Intravenous Tubing System

grateful for the opportunities this program offers to drive healthcare innovation and address the need for solutions that improve patient safety while also reducing clinical burdens.”

Hans Utz, Founder and CEO

About the FDA STeP Program

The FDA's Safer Technologies Program (STeP) is a voluntary program for certain medical devices and device-led combination products that are reasonable expected to significantly improve the safety of currently available treatments or diagnostics that target an underlying disease or condition associated with morbidities and mortalities less serious than those eligible for other programs, such as the Breakthrough Devices Program. Devices that are eligible for STeP, unlike those that are eligible for the Breakthrough Devices Program, may include devices that are intended to treat or diagnose diseases or conditions that may be non-life threatening or reasonably reversible.

The goal of STeP is to provide patients and healthcare providers with timely access to these medical devices by expediting their development, assessment, and review, while preserving the statutory standards for premarket approval, 510(k) clearance, and De Novo marketing authorization, consistent with the Agency's mission to protect and promote public health.

<https://www.fda.gov/medical-devices/how-study-and-market-your-device/safer-technologies-program-step-medical-devices#what>

About Lightengale

Lightengale is an Atlanta-based medical device company on a mission to reduce IVT mix-ups in ICUs, increasing nursing efficiency, reducing errors – and saving lives. Founded in 2016 by innovator and entrepreneur Hans Utz, the Company emerged in response to Mr. Utz's experience in observing ICU nurses caring for his infant son. As he watched nurses manually trace lines, he was alarmed, conscientious of the complexity, time involved and potential risks. As a formally trained industrial engineer, he recognized a practical solution: if nurses could easily see and distinguish an infusion line from pump to patient, the whole process to identify IVT would be faster and safer. Patient safety demands better solutions. Lightengale is illuminating the way. For more information visit lightengalehealth.com.

<https://lightengalehealth.com>

1Pinkney, S. et al. Multiple Intravenous Infusions Phase 2b: Laboratory Study. Ont Health Technol Assess Ser 14, 1-163 (2014)

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