

Lymphatica Medtech Receives FDA “Breakthrough Device Designation” for Its Innovative Implantable Lymphedema Treatment Technology

LAUSANNE (CH) | February 09, 2024 – Lymphatica Medtech SA, a leading medical device company pioneering advancements in lymphedema treatment, proudly announces the receipt of Breakthrough Device Designation from the U.S. Food and Drug Administration (FDA) for its revolutionary product, LymphoDrain. This breakthrough designation represents a significant milestone in the journey toward transforming the treatment landscape for chronic lymphedema.

Chronic lymphedema, characterized by debilitating swelling of limbs, poses a considerable challenge for millions worldwide, particularly those who have undergone cancer treatment involving lymph node removal or damage. LymphoDrain, an innovative implantable device, offers a promising solution to drain interstitial fluid from edematous limbs to areas with functional lymphatic vessels, thus addressing a critical unmet medical need in adult patients.

The FDA’s Breakthrough Device designation program facilitates an expedited review process for products demonstrating potential to provide more effective treatment for irreversibly debilitating diseases. LymphoDrain’s designation underscores its status as a breakthrough technology, offering significant advantages over existing alternatives, and prioritizes patient access to transformative therapies.

In response to the FDA decision, Marco Pisano, co-founder and CEO of Lymphatica Medtech, said: “Our mission at Lymphatica Medtech is to empower vascular doctors with innovative solutions that enhance patients’ health and quality of life. The FDA’s validation of LymphoDrain’s potential as a breakthrough therapy reaffirms our commitment to revolutionizing lymphedema treatment and alleviating the burden faced by patients worldwide.”

Lymphatica Medtech’s journey to FDA Breakthrough Device Designation was supported by a successful first-in-human clinical trial conducted in collaboration with the University Hospital of Lausanne (CHUV – Switzerland), led by Prof. Lucia Mazzolai. As part of the Breakthrough program, Lymphatica will benefit from expedited interactions with FDA experts, potentially accelerating the pathway to market.

About Lymphatica Medtech:

Lymphatica Medtech SA is a Swiss medical device company founded in July 2017, originating from the Swiss Federal Institute of Technologies, Lausanne (EPFL – Ecole Polytechnique Fédérale de Lausanne), and the Centre Hospitaliere Universitaire Vaudois (CHUV). Lymphatica Medtech pioneers breakthrough innovations in lymphedema treatment, dedicated to

enhancing patient outcomes and quality of life. For more information, visit www.lymphaticamedtech.com.

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