

FDA grants Breakthrough Device Designation to STIMIT Activator 1

STIMIT AG, part of the Hamilton Medical group, today announced that the U.S. Food and Drug Administration (FDA) has granted Breakthrough Device Designation to the STIMIT Activator 1.

The STIMIT Activator 1 is a temporary, noninvasive device designed to stimulate both phrenic nerves and activate the diaphragm in mechanically ventilated patients. It is intended to mitigate diaphragm atrophy, a structural manifestation of ventilator-induced diaphragmatic dysfunction (VIDD), in patients aged 21 years or older who are at risk of developing diaphragm atrophy/VIDD due to mechanical ventilation.

The Breakthrough Device Designation marks an important step in STIMIT's U.S. regulatory pathway. The FDA's Breakthrough Devices Program is designed for certain medical devices that may offer more effective treatment for life-threatening or irreversibly debilitating conditions compared with the current standard of care.

Through the program, STIMIT will benefit from more frequent interaction with FDA experts and prioritized review as it continues the clinical and regulatory work required for U.S. market authorization.

Strengthening STIMIT's presence in North America

To support this next phase, STIMIT is expanding its North American organization to support closer collaboration with clinical investigators, regulatory stakeholders, health systems, and Hamilton Medical teams in the United States and Canada.

"Receiving Breakthrough Device Designation is an important milestone for STIMIT and reflects the work of our team, our clinical partners, and our colleagues across Hamilton," said Ronja Bruhn, CEO of STIMIT. "Together, we are working toward a shared goal: advancing respiratory care while helping preserve patients' natural respiratory function."

Regulatory status

The designation does not constitute FDA clearance or approval; STIMIT Activator 1 remains an investigational device in the United States. Currently, STIMIT Activator 1 is licensed by Health Canada as a Class II medical device.

Characters incl. spaces 2'056

Words 291

About STIMIT

STIMIT AG develops noninvasive diaphragm stimulation technologies for patients receiving mechanical ventilation in critical care settings. Its technology uses noninvasive magnetic stimulation of the phrenic nerves to activate the diaphragm, the body's primary breathing muscle. STIMIT's mission is to empower patients to breathe and to advance critical care by helping preserve natural respiratory function. In 2026, STIMIT AG became part of the Hamilton Medical group.

About Hamilton Medical

In 1983, Hamilton Medical was founded with a vision: To develop Intelligent Ventilation solutions that make life easier for patients in critical care and for the people who care for them. Today, Hamilton Medical is a leading manufacturer of critical care ventilation solutions for a variety of patient groups, applications, and environments.

Contact

Hamilton Medical AG
Kathrin Elsner
Head of Marketing Communications

+41 (0) 58 610 12 80
media.med.global@hamilton-medical.com
www.hamilton-medical.com