



PRESS RELEASE

27 May 2026 11:15:00 CEST

From science to practice: Senzime obtains FDA 510(k) clearance for enhanced TetraGraph system

UPPSALA, Sweden – Senzime AB today announced that its TetraGraph® neuromuscular monitoring system has received an additional FDA Class II 510(k) clearance. The new FDA clearance follows submission in April 2026 and expands the system’s capabilities, further strengthening the TetraGraph’s competitive advantages.

The new 510(k) clearance includes, among other things, unique capabilities of the next-generation TetraGraph system, and additional innovations that will be introduced over time.

“This FDA clearance is an important milestone for Senzime, enabling broadened competitive advantages of current and future capabilities of the TetraGraph system,” said Philip Siberg, CEO of Senzime. “We continue to pioneer our industry by developing innovations that enhance patient safety, improve clinical workflows, and support more cost-effective care.”

The TetraGraph system is used by anesthesiologists in more than 750 hospitals worldwide to support patient safety during and after surgery. The system uses proprietary algorithms and advanced sensors to accurately monitor neuromuscular function during surgery. This helps clinicians to determine when it is appropriate to intubate patients, optimize dosing of neuromuscular blocking and reversal agents, and assess when patients are ready for extubation and spontaneous breathing after surgery.

For further information, please contact:

Philip Siberg, CEO of Senzime AB

Phone: +46 (0) 707 90 67 34, e-mail: philip.siberg@senzime.com

About Senzime

Senzime is a leading medical device company at the forefront of a changing healthcare market, driven by new clinical guidelines and emerging technologies. Established in 1999, Senzime develops and markets precision-based monitoring systems that improve outcomes, reduce costs, and advance perioperative patient safety. The flagship solution is the TetraGraph® system, proven best-in-class for accurate monitoring of neuromuscular transmission during surgery and used in thousands of operating rooms across the globe. The system helps to secure precise dosing of paralytic drugs and provides enhanced insights to safeguard every patient's journey, from anesthesia to recovery.

Headquartered in Uppsala, Sweden, Senzime is publicly traded on the Nasdaq Stockholm Main Market (SEZI), with cross-trading on the US OTCQX Market (SNZZF), and backed by long-term investors. More information is available at [senzime.com](https://www.senzime.com).

Attachments

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