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Gentherm Announces FDA 510(k) Submission for Innovative Technology Expected to Promote Safer Surgeries and Better Patient Outcomes

Feb 3, 2026

Market launch for its first of a kind integrated patient warming and securement system planned for third quarter of this year

NOVI, Mich., Feb. 03, 2026 (GLOBE NEWSWIRE) -- Gentherm (NASDAQ: THRM) a global market leader of innovative thermal management and pneumatic comfort technologies, today announced it submitted a 510(k) Class II premarket notification to the U.S. Food and Drug Administration (FDA) for ThermAffyx™ Patient Safety System, an integrated patient warming and securement system.

Two leading patient safety concerns during robotic surgery are maintaining patient temperature and preventing patient movement while on the operating room table. The first of its kind ThermAffyx™ System combines air-free patient warming with securement technology to help prevent both hypothermia and patient movement during procedures where it is common for the patient to be positioned in Trendelenburg. Trendelenburg is a tilted, head-down position that uses gravity to shift organs in the abdomen out of the way, giving the surgeon better access. In surgical settings, inadvertent hypothermia can dramatically increase the risk of surgical complications.

"Gentherm engineers began development after identifying this unmet clinical pain point and gap in the market," confirmed Steve Fletcher, Senior Vice President and General Manager, Gentherm Medical. "Until now, there hasn't been an all-in-one product that successfully resolves these patient safety concerns. Our innovation will define a new standard of care and improve patient outcomes."

This is the newest example of the company leveraging technology from its well-known automotive division to develop new systems for medical use.

"This concept is very intuitive and an exciting opportunity for those of us who spend so much time in operating rooms," says Dr. Perrin Jones, an anesthesiologist in North Carolina. "Taking the technology Gentherm uses in heated seats in cars and adapting it into a medical device that we can put under patients to help them stay warm and secure during surgery, will be a game changer in any operating room."

FDA clearance is expected within the first half of 2026.

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About Gentherm

Gentherm (NASDAQ: THRM) is a global market leader of innovative thermal management and pneumatic comfort technologies. Automotive products include Climate Control Seats (CCS®), Climate Control Interiors (CCI™), Lumbar and Massage Comfort Solutions, and Valve Systems. Medical products include patient temperature management systems. The Company is also developing a number of new technologies and products that will help enable improvements to existing products and to create new product applications for existing and new markets. Gentherm has more than 14,000 employees in facilities across 13 countries. In 2024, the company recorded annual sales of approximately \$1.5 billion and secured \$2.4 billion in automotive new business awards. For more information, go to www.gentherm.com.

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Source: Gentherm Inc