

MethodSense Supports ulrich medical to Fourth FDA Clearance for Innovative Computed Tomography (CT) Injector System

Collaboration underscores MethodSense's role in accelerating market access and regulatory confidence for advanced medical device innovations.

MORRISVILLE, NC, UNITED STATES, January 15, 2026 /EINPresswire.com/ -- [MethodSense](#), Inc., a leading regulatory and quality consulting firm for the medical device industry, announced today that its client [ulrich medical](#) has received its fourth FDA clearance for the ulrich medical CT Motion Injector, a next-generation, syringe-less injector system used in diagnostic imaging. This latest clearance marks another milestone in a long-standing partnership between MethodSense and ulrich medical, reflecting more than a decade of collaboration, innovation, and strategic regulatory leadership.

Since beginning work together in 2012, MethodSense has supported ulrich medical through complex FDA submissions involving combination products, multiple pharmaceutical partners, and highly technical contamination control and Human Factors studies.



ulrich medical CT Motion Injector



"This clearance represents more than regulatory success. It reflects the power of strategy, innovation, and collaboration," said Rita King, CEO and Senior Regulatory Strategist at MethodSense. "By aligning ulrich medical's engineering, quality, and regulatory processes under a unified strategy, we helped accelerate market access for an injector that improves workflow



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*Rita King, CEO of
MethodSense*

efficiency, reduces patient wait times, and enhances safety in radiology departments."

Breakthrough Features Recognized by FDA

The newly cleared CT Motion Injector System introduces several significant advancements designed to improve clinical efficiency, safety, and interoperability:

- Extended disposable usability: The injector's spikes can now remain in use for up to 24 hours (previously 8 hours), significantly reducing setup time and consumable waste.
- Expanded pharmaceutical capacity: The system now supports up to 36 contrast media bottles per pump tubing,

nearly doubling throughput and patient capacity compared to prior models.

- Broadened compatibility: Adds Iohexol IBP (ISOVUE IBP) by Bracco Diagnostics as a validated contrast medium, demonstrating the injector's ability to integrate with multiple pharmaceutical partners.
- Flexible labeling for indications for use: FDA clearance now references only the active pharmaceutical ingredient and container type, rather than specific product brands, offering greater clinical flexibility and simplified labeling updates.
- Automated contrast medium density: Introduces CDadapt, a new software function that autonomously reduces contrast media density (e.g., for cardiac examinations) by automatically adjusting contrast medium density within the tubing system without the need for manual steps, thus enhancing accuracy, workflow efficiency, and patient safety, while also lowering costs through reduced contrast media usage.

These updates nearly double the efficiency of prior models and solidify ulrich medical's competitive edge in the CT injector industry.

Proof of Long-Term Partnership and Market Growth

ulrich medical's collaboration with MethodSense has spanned multiple years, during which MethodSense supported the company through pre-submission meetings, contamination studies, and joint FDA reviews. In a short period of time since its first FDA submission in 2017, ulrich medical has expanded its U.S. market share and product portfolio, growing beyond the FDA's small business designation, a testament to the strength of its partnership with MethodSense and its commitment to innovation.

About MethodSense

MethodSense, Inc. is a regulatory and quality consulting firm specializing in medical devices and life sciences. Through its consulting expertise and LuminLogic regulatory management platform, MethodSense helps companies navigate global regulatory pathways, manage documentation and submissions, and accelerate time to market for innovative healthcare technologies.

Learn more at www.methodsense.com

About ulrich medical

ulrich medical, headquartered in Ulm, Germany, is a leading developer and manufacturer of innovative medical technology. Founded in 1912, the company specializes in contrast media injectors and spinal systems used worldwide in diagnostic imaging and surgical applications. ulrich medical products are recognized for their precision engineering, reliability, and focus on improving patient outcomes.

Learn more at www.ulrichmedical.com.

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