

## TeraRecon receives first-of-kind FDA determination



Advanced visualization and artificial intelligence (AI) technology provider, [TeraRecon](#), today announced it has successfully completed an FDA regulatory review of its Northstar™ AI Results Explorer, for which the technology and the determination are both firsts-of-kind in the medical imaging industry. Northstar is designed to work alongside the company's EnvoyAI™ interoperability platform which includes FDA-cleared 3rd party content listed on its EnvoyAI Exchange marketplace. The Northstar determination letter reinforces the company's commitment to regulatory and quality standards along with transparency in the field of medical imaging artificial intelligence.

The Northstar AI Results Explorer provides an engaging physician user experience which can be integrated into the clinical systems already used throughout the health enterprise. Now with full commercial availability, Northstar can provide physicians an important way to accept, reject, and interact with AI-derived findings. Through the EnvoyAI marketplace, health systems can enter into a single contractual agreement and confidently run algorithms interchangeably, with a single two-hour software installation.

EnvoyAI is the world's first AI marketplace and the only AI interoperability platform. EnvoyAI customers currently have access to over 80 algorithms with 20 holding regulatory clearances in various global territories.

"As the medical AI market continues to mature, global regulatory bodies are growing ever more vigilant and confident in assessing these emerging technologies" noted Patty O'Brien, Vice President Regulatory Affairs at TeraRecon. "It is gratifying to work in today's collaborative regulatory environment and to do our part as an industry partner in the process."

With deep domain expertise involving class II medical imaging software devices, TeraRecon maintains stringent processes, documentation and quality systems across its design, development and business operations. The FDA has determined that the Northstar AI Results Explorer is exempt from Class II premarket notification requirements and therefore is considered a Class I medical device alongside their existing Class I EnvoyAI platform.

"TeraRecon technologies are always designed keeping their future value in mind" said Jeff Sorenson, TeraRecon CEO. "We know that our artificial intelligence solutions are only the tip of the transformation iceberg and that workflows will only grow more sophisticated over time. Product requirements will continue to evolve and become deeply clinical and highly specialized, requiring much more than just a marketplace to deliver them. We expect any advanced AI workflow solutions will require the same level of diligence and sophistication as advanced visualization solutions do today, if not more" said TeraRecon CEO, Jeff Sorenson.

TeraRecon technologies including the EnvoyAI platform, TeraRecon Northstar AI Results Explorer, and its flagship iNtuition™ advanced visualization solution, will be on display at the Society for Imaging Informatics in Medicine (Book a demo at SIIM) in Aurora, Colorado from June 26th – June 28th, 2019. Online demonstrations are available by contacting TeraRecon at [info@terarecon.com](mailto:info@terarecon.com).

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