

TDi™ | SonoVision™ Receives 510(k) Clearance for the First Machine Learning Enabled Ultrasound Product in Spine Surgery



NEWS PROVIDED BY
[Tissue Differentiation Intelligence \(TDi\)](#) →
Apr 14, 2020, 10:03 ET



DELRAY BEACH, Fla., April 14, 2020 /PRNewswire/ -- Tissue Differentiation Intelligence, LLC (TDi™), a company specializing in real-time surgical ultrasound imaging, today announced receiving 510(k) clearance for the company's SonoVision™ ultrasound platform; the first technology of its kind specifically designed for intraoperative access to the spine.

By applying layers of image-processing algorithms to ultrasound images collected intraoperatively, SonoVision visually differentiates nerve, muscle, bone and vessels in real time. The FDA clearance of SonoVision paves the way for ultrasound to be used as a new imaging modality for spine surgery by overcoming the impracticalities of conventional ultrasound. "This is a monumental achievement for TDi which validates the rigor of the research and development process that has occurred over the past 7 years to make this technology possible. With this clearance, TDi ushers in a new era of innovations related to soft tissue imaging in spine surgery, and really, the beginning of a much broader trend of artificial intelligence and machine learning being applied to satisfy challenging clinical requirements in spine surgery. Congratulations to the TDi team of engineers, and to Drs. Kevin Foley, Kern Singh and David Schwartz for achieving this pivotal milestone." said Alex Lukianov, TDi Chairman and CEO, regarding the recent FDA clearance.

The company currently has multiple systems deployed for clinical study data collection under IRB and for Alpha evaluations, which are focused primarily on the clinical refinement of the lateral surgery access product. Expanded procedural applications, including posterior access to the spine, 3D imaging and image-guided navigation integration are also in earlier stages of procedural development.

The 510(k) clearance comes as part of a string of important milestones achieved in a relatively short period of time by TDi, including the issuance of strong intellectual property around the algorithm and procedural applications, as well as the completion of a porcine validation study. The issued intellectual property protects ultrasonically scanning tissue, interpreting images through signal and image processing, as well as algorithms used while differentiating tissue based on image characteristics and spectral signatures. "The significance of this level of protection for a machine learning product cannot be overstated – for most products of this nature, access to data-sets and trade-secrets are the front-line protections of the technology, which would conventionally be considered relatively weak protections. The issuance of this patent protecting the core functionality and procedural applications of SonoVision is unique and uncommon within the machine learning IP landscape." said Jonathan Spangler, Patent Counsel, about the Intellectual Property protection.

An in-vivo porcine study validating the accuracy of SonoVision in identifying the presence and absence of nerves within specimen psoas tissue was accepted for presentation by David Schwartz, MD at the SOLAS annual meeting. At the time of this release the meeting is postponed, however, the TDi research team is moving forward with submitting the study for peer-reviewed publishing.

With foundational clinical experience, 510(k) clearance, a strong patent portfolio, objective study validation and a robust technology pipeline, TDi looks forward to further accelerating commercialization efforts in 2020.

TDi Contact Information:

Christian Zaal
info@tissueintel.com

SOURCE Tissue Differentiation Intelligence (TDi)

Related Links

<http://www.tissueintel.com>



The SonoVision electronics platform displays an axial psoas muscle image with intuitive color differentiation of nerve, muscle and bone.