



enlightenVue's Single Use Micro-Endoscope complies with new FDA recommendations to increase patient safety.

The innovative micro-endoscope with multiple working channels is single use, eliminating the risk of transmitting infections among patients.

FRAMINGHAM, MASSACHUSETTS – October 21, 2019 – enlightenVue (<https://enlightenvue.com>), creators of a disposable platform of micro-endoscopes, announced that their product fully complies with the FDA's recommendation for the use of duodenoscopes with disposable components that include disposable endcaps, posing less risk to patient safety.

In a statement on August 29, 2019, Jeff Shuren, M.D., J.D., Director of the FDA's Center for Devices and Radiological Health said, "Duodenoscopes remain critical to life-saving care for many patients in the U.S. We are taking action because of continuing elevated levels of contamination in duodenoscopes."

enlightenVue's single-use micro-endoscope is packaged in its own sterile tray and does not require cleaning and/or re-sterilization, eliminating the risk of patient-to-patient transmission of microorganisms caused by difficulty in disinfecting and sterilizing re-usable endoscopes. To see this innovative micro-endoscope in action, click the video links below:



"We have developed a 2mm flexible, single-use micro-endoscope that addresses the concerns expressed by FDA in this and several other recommendations that the Agency has recently released regarding the risk of transmitting infections via re-usable endoscopes", said Giacomo Basadonna, Chief Executive Officer. "Our endoscope can be used in several surgical and medical applications including the endoscopy of the GI tract which is addressed by the current FDA concern. In addition, our endoscope is the only 2 mm instrument on the market that includes 2 working channels, which allow health care providers to perform interventional procedures via a minimal invasive approach and without being restricted only to diagnostic purposes."

The product is currently being reviewed by FDA for 510k clearance, which is expected in November 2019. Please direct inquiries to info@enlightenvue.com.



About enlightenVue

enlightenVue has developed a novel single use micro-endoscope that can be used for both diagnostic and interventional procedures with high definition like image quality. The micro-endoscope's unique high-intensity laser light can deliver up to 20 times the light of ordinary sources, while producing sharper images and better contrast. The high-intensity laser-light delivers cool, high-lux illumination that can be efficiently coupled into light channels that are coupled with fibers of the smallest size.

enlightenVue founders have a broad range of complimentary business experiences that provide for a well-rounded foundation for the Company. They include decades of experience in transplant surgery by one of the industry's thought leaders, nationally recognized developer and business strategist, and Wall Street investment banking. Our team members have previous experience in novel medical supplies and biopharmaceuticals.

By virtue of the innovation embodied in our products, enlightenVue has been able to attract highly experienced experts in areas including FDA regulatory submission; compliance-based manufacturing, medical device commercialization and intellectual property protection.

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