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enlightenVue's Single-Use Micro Endoscope Receives FDA 510(k) Clearance

The novel single-use micro-endoscope with multiple working channels, eliminates the risk of transmitting infections between patients.

FRAMINGHAM, Mass., March 31, 2020 /PRNewswire/ -- enlightenVue™ (<https://enlightenvue.com>), creators of the surgiVue™ single-use platform of micro endoscopes announced today that their product has received 510(k) marketing clearance from the Federal Drug Administration (FDA).

According to the FDA: "The use of the enlightenVue Microendoscopy System is intended for the visualization of body cavities, hollow organs, and canals. It is also designed to be introduced through natural body orifices cavities or surgical incisions through introducers, trocars, needles, sheaths, or other devices with lumens having inside diameters larger than the outer diameter of the endoscope."

Receiving this broad and general indication from the FDA gives enlightenVue the ability to market the unique surgiVue endoscope for multiple clinical and surgical procedures. EnlightenVue will immediately pursue several clinical trials in numerous medical and surgical specialties.

"This is the only two millimeter, single-use micro endoscope on the market with two working channels," said Giacomo Basadonna, Chief Executive Officer. "The surgiVue endoscope will protect patients from the risk of hospital-acquired infections that can be contracted from reusable endoscopes, as indicated by several FDA guidance documents. Additionally, the presence of two working channels allows health care providers to perform interventional procedures (rather than simple diagnostic ones) in a minimally invasive setting."

"We are proud to have enlightenVue as an Alira Health Ventures portfolio company and are impressed with the speed and efficiency

with which they achieved FDA clearance," said Gabriele Brambilla, Chief Executive Officer of Alira Health and head of the firm's investment arm, Alira Health Ventures. "It has only taken two and a half years from the initial sketch to 510(k) clearance, and this incredible technology is now poised to disrupt the market and offer a new level of safety and protection to patients."

EnlightenVue's micro endoscope is single-use and does not require cleaning and/or re-sterilization, eliminating the risk of patient-to-patient transmission of microorganisms caused by difficult to disinfect and sterilize reusable endoscopes. This is of importance during the current viral pandemic where direct contagion must be avoided. In addition, the single-use surgiVue endoscope provides financial advantages to the healthcare system by eliminating the sterilization, repair and personnel costs associated with reusable endoscopes, reducing downtime and inventory logistics. The novel micro-endoscope allows for a combination of diagnostic and interventional procedures, simplifies the patient's overall experience from diagnosis to treatment, and gives the provider a wide range of clinical options.

Please direct inquiries to info@enlightenvue.com.

About enlightenVue

EnlightenVue developed a novel single-use micro endoscope that can be used for both diagnostic and interventional procedures with high-definition 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 paired with fibers of the smallest size.