GI View Ltd. Receives FDA 510(k) Clearance for the New Aer-O-Scope® Disposable Colonoscope System with Working Channels for Therapeutic Intervention During Colorectal Cancer Screening

Aer-O-Scope is the only single use, self-propelled Colonoscope with a 360° omni-directional view of the colon.

Ramat Gan, Israel, September 20, 2016 --- GI View Ltd., developer of advanced GI screening systems, announced today that it has received FDA 510(k) clearance for the new Aer-O-Scope® Colonoscope System, a disposable, self-propelled, joystick-controlled, easy-to-use colonoscope system, now with therapeutic access. The new system has two working channels that enable therapeutic access using standard tools, such as snares and forceps, to take biopsies or perform polypectomies.

“Today’s news marks the achievement of an important regulatory milestone. The new Aer-O-Scope system with therapeutic access has many significant clinical benefits including enabling physicians to more easily, effectively and efficiently identify and remove polyps and prevent colon cancer,” said GI-View CEO Tal Simchony, Ph.D. EE. “We are now working on US market introduction of the Aer-O-Scope. Post market studies are also in the plans.”

The Aer-O-Scope is the first colonoscope to provide a 360° omni-directional visualization of the colon to detect polyps behind folds. There is also no risk of contamination or disease transmission between patients from the device as it is to be used only once and then disposed. The Aer-O-Scope employs a soft multi-lumen tube designed to significantly reduce pressure on the colon wall, which in turn, increases patient safety. The tube is also hydrophilic, which reduces the friction between bowel and scope by more than 90%. Patient safety and comfort as well as physician ease of use are further maximized by the system’s self-propelled intubation, created using balloons and low pressure CO₂ gas. As the system is joystick controlled it is also extremely simple to operate and requires minimal training. Like all colonoscopes, the Aer-O-Scope provides insufflation, irrigation and suction.
Colorectal cancer is one of the biggest causes of cancer death in most countries in the West. This type of cancer can almost always be prevented by early detection and removal of polyps, which if left untouched, can develop into colorectal cancer over a 5-10 year period. More than 690,000 people worldwide die from colorectal cancer annually.

About GI View Ltd.
Headquartered in Ramat Gan, Israel, GI-View Ltd. is dedicated to fundamentally advancing the efficiency, accuracy and comfort of colorectal cancer screening. The company’s flagship product is the Aer-O-Scope Colonoscope System, the only disposable colonoscope with a 360° omni-directional view for colon cancer screening. GI-View has been granted ISO certification for quality systems. The new Aer-O-Scope® Colonoscope System is FDA cleared for market. The company has 55 granted patents and dozens more pending. Investors include: Israel HealthCare Ventures Ltd., Ziegler Meditech Equity Partners, Kemper Insurance and private investors. For more information and to view the product video, please visit: http://www.giview.com

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