



Avantis Medical Systems Announces FDA 510(k) Clearance for the Third Eye® Retroscope® for Improved Polyp Detection in the Colon

SUNNYVALE, California – February 17, 2009 – Avantis Medical Systems, Inc., a technology leader in developing novel chip-on-catheter digital imaging devices, announced today that it has received a new 510(k) clearance for its Third Eye® Retroscope® (Third Eye), supporting the claim for increased detection of cancerous and pre-cancerous polyps in the colon. This is the first technology that has been cleared by the FDA to enhance polyp detection when used in conjunction with the gold standard in colonoscopy.

“FDA clearance of our new 510(k) is important to physicians and patients alike because it acknowledges the value of the Third Eye in providing physicians an additional view of the colon, which enables them to detect more polyps than colonoscopy alone,” said Scott Dodson, President & CEO of Avantis Medical. “We are excited about the demonstrated capability of our device and its potential for saving lives.”

Colorectal cancer is the second leading cause of cancer death in the US and Europe.¹ However, most cancers of the lower gastrointestinal (GI) tract can be successfully treated if detected early. Even more cases can be prevented if pre-cancerous polyps are removed before they become malignant. Every year tens of millions of people have a colonoscopy to screen for colorectal cancer.

Colonoscopy is widely regarded as the “gold standard” for detection of abnormalities in the colon. However, research has revealed that 12-24 percent of polyps and a significant number of cancers can be missed during colonoscopy.^{2 3 4}

Furthermore, a recent large study analysis involving more than 10,000 cancer patients who died of colorectal cancer indicated that colonoscopy missed about one-third of colorectal cancers (CRCs) on the left side of the colon and 40-67 percent of the CRCs on the right side of the colon.⁵ The authors stated that, of the study patients who later passed away from CRC, more than twice the number of patients had polyps on the right-side of the colon vs. the left side.

The Third Eye Retroscope is indicated for use with colonoscopy to provide the physician with an additional view of the colon for diagnostic and detection purposes. When the Third Eye is deployed through the instrument channel of a standard colonoscope, it provides the physician with a retrograde view of the colon along with the forward (colonoscope) view. Operating as a “rear view mirror” the Third Eye helps visualize blind spots in the colon that may not be seen with the colonoscope alone. The device is commercially available to physicians who perform colonoscopies.

¹ According to the European Cancer Patient Coalition, Health First Europe and the American Cancer Society.

² Pickhardt, P.J.; Nugent, P.A.; Mysliwiec, P.A.; et al. Location of adenomas missed by optical colonoscopy. *Annals of Internal Medicine* 141(5):352-360, 2004.

³ Pabby, A.; Schoen, R.E.; Weissfeld, J.L.; et al. Analysis of colorectal cancer occurrence during surveillance colonoscopy in the dietary Polyp Prevention Trial. *Gastrointestinal Endoscopy* 61(3):385-391, 2005.

⁴ Rex, D.K.; Cutler, C.S.; Lemmel, G.T.; et al. Colonoscopic miss rates of adenomas determined by back-to-back colonoscopies. *Gastroenterology* 112(1):24-28, 1997.

⁵ Baxter, N.N.; Goldwasser, M.A.; Paszat, L.F.; Saskin, R.; Urbach, D.R.; Rabeneck, L. To evaluate the association between colonoscopy and CRC deaths. *Annals of Internal Medicine* 150:1-8, 2009

Avantis Medical Receives Expanded FDA 510(k) Clearance for the Third Eye® Retroscope®

“Our national study indicated that the Third Eye Retroscope, when used in combination with a standard forward-viewing colonoscope, revealed areas that are often hidden from the standard colonoscope,” said Douglas K. Rex, MD, Third Eye investigator, Chancellor's Professor and Professor of Medicine at Indiana University School of Medicine, and Director of Endoscopy at Indiana University Hospital in Indianapolis. “The device also enabled detection of 13.0 percent more polyps and 10.9 percent more adenomas than the colonoscope alone.⁶ These results are important to doctors and patients because most cases of colon cancer arise from adenomas.”

In addition to overall improvement in polyp detection, the Third Eye has shown to be equally effective in detecting polyps on both the right-side and the left-side of the colon, when compared to the colonoscope alone.⁷

About Avantis Medical Systems, Inc. and Third Eye® Retroscope®

Avantis Medical Systems, Inc. is focused on delivering cost effective solutions for improved detection and prevention of cancers of the gastrointestinal (GI) tract. The company's FDA cleared, CE Marked, Third Eye Retroscope is a novel, disposable, chip-on-catheter digital imaging device, designed to complement visualization provided by most standard colonoscopes for detection of cancer in the colon.

The “chip-on-catheter” platform of the Third Eye Retroscope is also the basis for other products under development by Avantis Medical to screen, assess and treat cancers throughout the body. Avantis Medical has an extensive portfolio of patents covering innovative devices based on the convergent technologies of micro-chips, enhanced video processing and catheter based delivery systems. For more information, visit www.avantismedical.com or www.getthirdeye.com.

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⁶ Waye, J.D.; Rex, D.K.; et al. The Third Eye Retroscope Auxiliary Endoscopy System Improves Detection of Polyps in the Colon – A Prospective Efficacy Evaluation. *Endoscopy* Supplement No. I(40): A24, OP1111, 2008.

⁷ Study on file with Avantis Medical Systems, Inc.