

US approves pill camera to screen colon (Update)

February 3 2014, by Matthew Perrone

A kinder, gentler approach to one of the most dreaded exams in medicine is on the way: U.S. regulators have cleared a bite-size camera to help screen patients who have trouble with colonoscopies.

The ingestible pill camera from Given Imaging is designed to help doctors spot polyps and other early signs of colon cancer. The Food and Drug Administration cleared the device for patients who have had trouble with the cringe-inducing colonoscopy procedure, which involves probing the large intestine with a tiny camera embedded in a four-foot long, flexible tube.

The Israeli company's technology, developed from missile defense systems, uses a battery-powered camera to take high-speed photos as it slowly winds its way through the intestinal tract over eight hours. The images are transmitted to a recording device worn around the patient's waist and later reviewed by a doctor.

While Given's wireless, image-beaming system may sound like science fiction, it's actually more than a decade old. In 2001, the company received FDA approval for a similar device used to get a close-up view of the small intestine.

At that time, analysts expected Given's approach to grow into a direct competitor to traditional colonoscopy. But company studies found that images taken by the mini-camera were not quite as clear as those from the in-office procedure. As a result, the company has pursued a more

limited market for its device: patients who have trouble undergoing standard colonoscopies.

The FDA on Monday cleared the company's PillCam Colon for patients who have experienced an incomplete colonoscopy. Given estimates 750,000 U.S. patients are not able to complete the procedure each year, due to anatomy issues, previous surgery or various colon diseases.

Even with this limited indication, analysts estimate the new pillcam could grow to sales of over \$60 million in North America by 2019, with room for expansion as the technology improves. MorningStar analyst Debbie Wang said the company has shrewdly positioned the device as another tool in the gastrointestinal specialist's kit, rather than a direct competitor.

"Given's management understands that the traditional colonoscopy is the gastroenterologist's bread and butter right now," Wang said. "So they didn't want to do anything that would position this as a substitute."

Wang notes that Given's PillCam costs \$500, significantly less than the roughly \$4,000 rate for colonoscopy. Eventually, she thinks doctors may use the device to attract adults who avoid regular screenings due to fears of pain, embarrassment and general discomfort. The Centers for Disease Control and Prevention's guidelines currently recommend regular colonoscopies beginning at age 50 and continuing through age 75, though most U.S. adults don't follow the recommendations.

In December, Irish medical device firm Covidien said it would buy Given for about \$860 million. Given Imaging, headquartered in Yoqneam, Israel, markets seven lines of medical devices and surgical supplies, including pillcams to screen the esophagus and small intestine.

Pillcam Colon was previously approved in 80 other countries, including

in Japan, Europe and Latin America.

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