

Japanese nod for Given Imaging's PillCam SB 3

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Singapore: Israel -based Given Imaging, makers of gastrointestinal medical devices and pioneer of capsule endoscopy, has announced that Japan's Pharmaceuticals and Medical Devices Agency (PMDA) has granted approval for the PillCam SB 3 system. The innovative technology in this third-generation system will provide physicians throughout Japan, the world's second largest healthcare market, with the most advanced PillCam capsule endoscopy technology to detect and monitor small bowel diseases, such as Crohn's disease.

The PillCam SB 3 capsule is a minimally invasive procedure to visualize and monitor small bowel abnormalities associated with Crohn's disease, iron deficiency anemia (IDA) and obscure GI bleeding (OGIB). The PillCam measures 11 mm x 26 mm and weighs less than four grams. Now, in its third generation, PillCam SB 3 contains an imaging device and light source and transmits images at a rate between two and six images per second.

"Approval of the PillCam SB 3 system in Japan underscores our global commitment to providing physicians with innovative tools to detect and monitor abnormalities of the gastrointestinal tract," said Mr Homi Shamir, president and CEO, Given Imaging. "The approval of the PillCam SB 3 system in Japan builds upon our recent regulatory momentum that includes PillCam COLON in Japan and PillCam SB 3 in the US Japan is a critically important healthcare market and we look forward to working with physicians there to integrate PillCam SB 3's benefits into clinical practice," he added.

Each component of the PillCam SB 3 system, including the capsule, recorder, sensor belt, and software, has been enhanced to work together to improve image quality, tissue coverage and efficiency. New adaptive frame rate technology also allows the capsule to automatically increase the rate at which images are taken when it senses it is moving more quickly through the digestive tract. Improvements in the new system's RAPID for PillCam software enable even smarter video compilation which is 40 percent more efficient than with PillCam SB 2. The company expects to begin recognizing sales of PillCam SB 3 in Japan in 2014.

"With its higher resolution and improvement in capturing images of the small bowel mucosa, the new PillCam SB 3 capsule endoscopy system provides us with enhanced performance and efficiency," said Dr Tetsuya Nakamura, professor and director, Department of Medical Informatics, Dokkyo Medical University. "With these improvements, along with recently receiving an expanded indication, PillCam SB will continue to play an important role in the diagnosis and treatment of small bowel diseases in Japan," Dr Nakamura added.