

# AnX Robotica Receives FDA DeNovo Classification for NaviCam™ Remote-Controlled Capsule Endoscopy System for the Stomach

*Magnetically Controlled Capsule Endoscope (MCCE) system enables complete-real-time visualization of the stomach for the first time.*

PLANO, TX, UNITED STATES, June 4, 2020 /EINPresswire.com/ -- AnX Robotica Corporation today announced it has been granted by the Food and Drug Administration (FDA) De-Novo classification for its NaviCam™ Magnetically Controlled Capsule Endoscopy (MCCE) System. The first-of-its-kind system allows complete, real-time visualization of the stomach utilizing a pill-sized capsule containing a camera and is remote-controlled by the physician using proprietary magnetic technologies.

Traditional capsule endoscope is propelled by natural motility of the digestive tract while the stomach is also affected by gravity, limiting complete visualization of the stomach. The NaviCam™ MCCE System is the first device that enables maneuverability and control of a camera inside the stomach from outside of the body by magnetic remote control. Additionally, the system offers a significant advantage over traditional methods by overcoming the need for sedation, which has been associated with post-procedural side effects.

“The NaviCam™ MCCE System provides gastroenterologists a convenient and non-invasive alternative to endoscopy to obtain images of the interior of the stomach to provide information that can help diagnose a patient’s symptoms,” said Raman Muthusamy, M.D., Professor of Clinical Medicine at the David Geffen School of Medicine at UCLA. “The magnetic control may improve imaging of the entire stomach and offers a novel alternative for patients who are hesitant to undergo traditional endoscopy.”

“The NaviCam™ MCCE System has the potential to be a valuable tool to manage patients presenting to an Emergency Department or Urgent Care with upper gastrointestinal complaints because it enables rapid visualization of the stomach which may lead to more accurate triage of emergency care,” said Andrew Meltzer, M.D. Emergency Medicine, George Washington University Hospital. “In addition, for patients who may have an infectious disease such as COVID-19, the use of NaviCam™ MCCE enables the treating physician to perform an endoscopic examination while reducing his or her physical proximity to the patient which may lead to a decreased risk of

infection for the clinician.”

“We are excited to introduce our NaviCam™ MCCE System into the United States to provide a non-invasive and patient-friendly tool for U.S. physicians to help a broad range of patients experiencing gastrointestinal symptoms and may benefit from complete visualization of their stomach. We are proud to bring to market this first-of-its-kind technological advancement to Gastroenterologists and Emergency Care Physicians” said Kevin Rubey, Chief Strategy Officer for AnX Robotica.

The NaviCam™ System is installed in more than 1,000 locations around the world with over 500,000 patients benefiting from the procedure. Numerous studies have been completed, including 28 peer-reviewed publications with more than 6,000 patients. Additional clinical trials are ongoing in the United States, Europe, and Asia.

#### About AnX Robotica

AnX Robotica develops and provides non-invasive and minimally invasive products for the benefit of patients around the world by providing advanced technologies to physicians. AnX is a global medical technology leader committed to innovation through application of advanced technologies and high-performance solutions to address patient needs and reduce the cost of healthcare. For more information visit [www.anxrobotics.com](http://www.anxrobotics.com).

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