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China's SonoScape receives FDA 510(k) clearance for HD-550 Endoscopy system

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SonoScape announced that the U.S. Food and Drug Administration (FDA) has approved its flagship video endoscopy system HD-550 for gastrointestinal diagnosis, setting up a major milestone on SonoScape's Endoscopic product roadmap.

Paired with a 4-LED light source, which supports 1080P high definition, the HD-550 endoscopy system enables multi-spectrum and multi-mode. Adding to the high-performing white-light mode, its chromoendoscopy SFI (Spectral Focused Imaging) and VIST (Versatile Intelligent Staining Technology) light modes enhance vascular and mucosal color contrast. As a result, more details in the GI tract can be revealed, which may help doctors in detection, demarcation, and characterization of the lesions. Included in the clearance are the 550 series videoscopes, whose maneuverability has been endorsed by top endoscopists around the world.

The HD-550 endoscopy system has been available outside of the USA since 2019. By 2021, HD550's top-of-the-line features and quality combined with its versatility saw it installed in close to 40 countries around the world and has made SonoScape the third best-selling brand in China.