



Cosmo Intelligent Medical Devices Unveils Next Generation GI Genius™ Hardware with New FDA Clearance

Dublin, Ireland – 31 July 2024: Cosmo Intelligent Medical Devices (Cosmo IMD), a division of Cosmo Pharmaceuticals N.V. (SIX: COPN, XETRA: C43) (“Cosmo”) focused on pioneering medical devices powered by Artificial Intelligence, announced today that the U.S. Food and Drug Administration (FDA) has granted 510(k) clearance for the next generation GI Genius™ hardware, the latest development of the GI Genius™ intelligent endoscopy system, which Medtronic exclusively distributes globally. This milestone reaffirms the GI Genius™ platform’s leadership in AI-enhanced endoscopy and marks a significant advancement in the realm of medical technology.

The GI Genius™ hardware, now in its sixth generation, is engineered to elevate physician performance with sophisticated AI-driven insights during patient procedures. This latest iteration includes the FDA-cleared ColonPRO™ software, the GI Genius™ AI colon application designed to help endoscopists identify potential polyps and standardize quality metric reporting during colorectal cancer screenings.

Revolutionary features of the latest GI Genius™ hardware:

- **Enhanced AI Capabilities:** The module extends the platform’s ability to support innovations in AI and enables acceleration towards exciting new AI features.
- **Versatile AI App Integration:** The module is capable of hosting multiple AI apps, significantly broadening the platform’s utility, through a developer program led by Cosmo IMD with Medtronic’s¹ commercial leadership. See [link](#).
- **Improved Connectivity:** With additional interconnectivity options, the GI Genius™ hardware potentially integrates seamlessly within the healthcare system to standardize quality metrics and procedure highlights.
- **Energy Efficiency:** The innovative design of the module achieves more with less energy, ensuring a quiet, efficient, and environmentally friendly operation.
- **Reliable Performance:** It integrates hardware technologies to support real-time performance during medical procedures and an extended product lifecycle.

These advancements were realized through Cosmo IMD’s meticulous engineering, utilizing state-of-the-art components such as NVIDIA IGX Orin™ and NVIDIA Holoscan™ technologies.

The GI Genius™ hardware represents a new frontier in endoscopic technology, providing healthcare professionals with continuously evolving AI capabilities to enhance patient care. This advancement underscores Cosmo Intelligent Medical Devices’ commitment to staying at the forefront of innovation and excellence in healthcare.

¹Existing GI Genius™ hardware can also be upgraded to host multiple independent AI applications. More communication with current customers will be forthcoming.



Nhan Ngo Dinh, President of Cosmo Intelligent Medical Devices commented: *“The GI Genius™ system sets a new standard in endoscopic technology. Our continuous innovation is driven by a commitment to enhancing patient care through AI. This FDA clearance marks a significant achievement, reinforcing our leadership in the field and our dedication to providing physicians with the tools they need to deliver exceptional medical outcomes.”*

About Cosmo

Cosmo is a pharmaceutical company focused on developing and commercializing products to treat selected gastrointestinal disorders, to improve endoscopy quality measures through aiding the detection of colonic lesions, and to treat selected dermatological conditions. Cosmo develops and manufactures products which are distributed globally by selected partners including Lialda®/Mezavant®/Mesavancol®, Uceris®/Cortiment®, Aemcolo®/ Relafalk®, Lumeblue® and Winlevi®. Cosmo has also developed medical devices for endoscopy and has a partnership with Medtronic for the global distribution of GI Genius™ which uses artificial intelligence to help detect potential signs of colon cancer. The company also has a rich development pipeline. For additional information on Cosmo and its products please visit the Company's website: www.cosmopharma.com.

Upcoming Calendar of Events

H.C. Wainwright Global Investment Conference, N.Y.
UBS Global Healthcare Conference, California

September 9-11, 2024
November 11-14, 2024

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