



Aptar Digital Health Announces FDA 510(k) Clearance for HeroTracker® Sense, a Connected Add-On Device for Metered-Dose Inhalers

Crystal Lake, Illinois, October 16, 2025 – Aptar Digital Health, a global leader in digital health solutions enhancing the patient experience, today announced that the U.S. Food and Drug Administration (FDA) has granted 510(k) clearance for HeroTracker® Sense as a Class II medical device. This milestone recognizes HeroTracker® Sense - a Bluetooth-enabled sensor - as an innovative connected add-on for pressurized Metered Dose Inhalers (pMDIs), transforming traditional inhalers into smart, data-driven devices for patients and healthcare professionals.

Designed for individuals aged 12 and above, HeroTracker® Sense is compatible with several commonly prescribed asthma and chronic obstructive pulmonary disease (COPD) medications, including Ventolin® HFA, Advair®, and certain albuterol and fluticasone/salmeterol inhalers. Integrated within [Aptar Digital Health's Respiratory Disease Management Platform](#), HeroTracker® Sense supports users in managing their respiratory health through comprehensive medication and symptom management. The platform delivers real-time usage tracking, personalized reminders and educational resources via an intuitive mobile application, encouraging behavior change and adherence to prescribed therapies. By enabling patients to monitor inhaler techniques and receive instant feedback, the platform aims to support improved respiratory health.

“By combining inhalation therapy with advanced digital health solutions, we aim to support patients in improving adherence and providing healthcare professionals with actionable insights,” said Raffi Krikorian, SVP Global Quality and Regulatory Affairs at Aptar Digital Health. “Our platform has previously shown promise in supporting asthma management and reducing reliance on rescue medication¹. The U.S. FDA's clearance allows us to enable broader access to our connected solutions for patients seeking to better manage their respiratory health.”

Asthma remains a significant health concern in the United States, affecting an estimated 26.8 million people across the United States². It stands among the leading causes of missed school and workdays, contributing to an economic burden of nearly \$82 billion each year in medical costs, lost productivity and premature death. With the FDA clearance of HeroTracker® Sense, individuals living with asthma or COPD will now have access to an innovative and user-friendly solution for tracking, evaluating and recording their medication use, aiming to improve treatment outcomes and quality of life.

About HeroTracker® Sense

HeroTracker® Sense is a connected add-on device attached to a compatible pressurized Metered Dose Inhaler (pMDI) for patients aged 12 and above. It functions as an electronic data capture accessory for monitoring and recording individual inhalation actuation, shake, orientation, coordination, and inspiratory strength and duration during prescribed inhaler use. HeroTracker® Sense is designed to operate with specific pMDI and medication indicated on the label. It does not provide information on the remaining quantity of medication in the inhaler and does not include a dose-counting function. HeroTracker® Sense does not provide

¹ Bijlani A, Mauger D, Goodheart C, dOrsay G, Suman J. Impact of a digital therapeutic on adult asthma. Eur J Public Health. 2023 Oct 24;33(Suppl 2):ckad160.823. doi: 10.1093/eurpub/ckad160.823. PMID: PMC10597004.

² [Most Recent National Asthma Data | CDC](#)



Press Release



spirometry measurements. HeroTracker® Sense may be used in clinical practice or clinical trials, where specialists require insights into whether a patient has used their prescribed medication or to assess inhalation technique.

About Aptar Digital Health

Aptar Pharma's Digital Health division is part of AptarGroup, Inc. (NYSE:ATR), a global leader in drug and consumer product dosing, dispensing and protection technologies. Aptar Digital Health creates end-to-end solutions to enhance patient experiences every day, leveraging a holistic ecosystem of digital interventions. Amplified by an industry-leading portfolio of products and solutions, Aptar Digital Health's offering combines mobile and web apps, Software-as-Medical-Device, connected drug delivery systems, advanced data analysis services, and patient onboarding and training solutions to actively empower patients and create a positive treatment journey. Aptar is headquartered in Crystal Lake, Illinois and has more than 13,000 dedicated employees in 20 countries. For more information, visit www.aptdigitalhealth.com and www.aptar.com.

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