June 30, 2025

Voluntis
% Rachel Paul
Lead Quality and Regulatory Affairs Consultant
Emergo Global Consulting
LLC 2500 Bee Cave Road Building 1
Austin, Texas 78746

Re: K250022
Trade/Device Name: HeroTracker Sense
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer
Regulatory Class: Class II
Product Code: CAF
Dated: January 3, 2025
Received: January 3, 2025

Dear Rachel Paul:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

John S. Bender -S
2025.06.30 12:39:13 -04'00'

for Ethan Nyberg, Ph.D.
Assistant Director
DHT1C: Division of Anesthesia,
Respiratory, and Sleep Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT, and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K250022

Device Name

HeroTracker Sense

Indications for Use *(Describe)*

The HeroTracker Sense Device (HTS) is an add-on device which is attached by patients on a metered-dose inhaler (MDI).
HTS is intended for single-patient multiple use in the home environment as an electronic data capture accessory for monitoring and recording actuation, inhaler shake, inhaler orientation, inhalation coordination, and inspiratory strength and duration for prescribed inhaler usage.
HTS may be used in the following applications: in clinical practice or clinical trials, where specialists, general practitioners, nurses and educators need to know if a patient has used their prescribed medication or assess inhaler technique.
HTS is designed to work only with the MDI and medication indicated on the HTS label.
HTS is not intended to indicate the remaining quantity of medication in an inhaler and does not include a dose counting function.
HTS is not intended to provide spirometry measurements.
HTS is intended to be used by Metered Dose Inhaler (MDI) users aged 12 years and over.

Compatible Medication - Strength and Dose Account
Ventolin 90 mcg HFA (60 count)
Advair 45 mcg / 21 mcg (120 count)
Advair 115 mcg / 21 mcg (120 count)
Advair 230 mcg / 21 mcg (120 count)
Albuterol Sulfate (Prasco) 90 mcg (200 count)
Fluticasone Propionate & Salmeterol 45 mcg / 21 mcg (120 count)
Fluticasone Propionate & Salmeterol 115 mcg / 21 mcg (120 count)
Fluticasone Propionate & Salmeterol 230 mcg / 21 mcg (120 count)
Albuterol Sulfate (Lupin) 90 mcg (200 count)

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

510(k) Summary

HeroTracker Sense (HTS)

1. Submission Sponsor

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75017 Paris
France
Sana Charnine, Regulatory Affairs and Quality Manager, Aptar Digital Health

2. Submission Correspondent

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Austin, TX 78746
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Contact: Rachel Paul
Title: Lead Quality and Regulatory Affairs Consultant

3. Date Prepared

30 June 2025

4. Device Identification

Trade/Proprietary Name:	HeroTracker® Sense
Common/Usual Name:	Nebulizer Accessory
Regulation Number(s):	868.5630
Product Code(s):	CAF, Nebulizer (Direct Patient Interface)
Class:	Class 2
Classification Panel:	Anesthesiology

5. Legally Marketed Predicate Device(s)

Device name: Hailie® Sensor NF0110
510(k) number: K222247
Manufacturer: Adherium (NZ) Ltd

6. Device Description

The HeroTracker Sense (HTS) is a nebulizer accessory. It is an add-on device which is attached by patients on a metered dose inhaler (MDI) and is used to record and analyze data related to medication actuation and technique of use for prescribed inhaler usage. Data is transferred to a mobile application with appropriate settings and is displayed to end users.

7. Indication for Use Statement

The HeroTracker Sense Device (HTS) is an add-on device which is attached by patients on a metered-dose inhaler (MDI).

HTS is intended for single-patient multiple use in the home environment as an electronic data capture accessory for monitoring and recording actuation, inhaler shake, inhaler orientation, inhalation coordination, and inspiratory strength and duration for prescribed inhaler usage.

HTS may be used in the following applications: in clinical practice or clinical trials, where specialists, general practitioners, nurses and educators need to know if a patient has used their prescribed medication or assess inhaler technique.

HTS is designed to work only with the MDI and medication indicated on the HTS label.

HTS is not intended to indicate the remaining quantity of medication in an inhaler and does not include a dose counting function.

HTS is not intended to provide spirometry measurements.

HTS is intended to be used by Metered Dose Inhaler (MDI) users aged 12 years and over.

Compatible Medication	**Strength and Dose Account**
Ventolin	90 mcg HFA (60 count)
Advair	45 mcg / 21 mcg (120 count)
Advair	115 mcg / 21 mcg (120 count)
Advair	230 mcg / 21 mcg (120 count)
Albuterol Sulfate (Prasco)	90 mcg (200 count)
Fluticasone Propionate & Salmeterol	45 mcg / 21 mcg (120 count)
Fluticasone Propionate & Salmeterol	115 mcg / 21 mcg (120 count)
Fluticasone Propionate & Salmeterol	230 mcg / 21 mcg (120 count)
Albuterol Sulfate (Lupin)	90 mcg (200 count)

8. Substantial Equivalence Discussion

The following table compares the HTS to the predicate device with respect to indications for use, principles of operation, technological characteristics, materials, and performance, and forms the basis for

the determination of substantial equivalence. The subject device does not raise any new questions of safety or effectiveness as compared to the predicate device.

Comparison of Characteristics

Attribute	**Subject:** **HeroTracker Sense® v1.2**	**Predicate:** **Hailie® Sensor NF0110** **K222247**	**Comparison**
Product Code	CAF	CAF	Same
Regulation Number	868.5630	868.5630	Same
Intended for Use	Nebulizer accessory for recording nebulizer use and technique	Nebulizer accessory for recording nebulizer use and technique	Same
Indications for Use	The HeroTracker Sense Device (HTS) is an add-on device which is attached by patients on a metered-dose inhaler (MDI). HTS is intended for single-patient multiple use in the home environment as an electronic data capture accessory for monitoring and recording actuation, inhaler shake, inhaler orientation, inhalation coordination, and inspiratory strength and duration for prescribed inhaler usage. HTS may be used in the following applications: in clinical practice or clinical trials, where specialists, general practitioners, nurses and educators need to know if a patient has used their prescribed medication or assess inhaler technique. HTS is designed to work only with the MDI and medication indicated on the HTS label. HTS is not intended to indicate the remaining quantity of medication in an inhaler and does not include a dose counting function. HTS is not intended to provide spirometry measurements. HTS is intended to be used by Metered Dose Inhaler (MDI) users aged 12 years and over. **Compatible Medication** / **Strength and Dose Account** Ventolin / 90 mcg HFA (60 count)	The Hailie sensor is intended for single-patient multiple use in the home environment as an electronic data capture accessory for monitoring and recording actuation, inspiratory flow and inhaler shake for prescribed inhaler usage. The Hailie sensor may be used in the following applications: in clinical practice or clinical trials, where specialists, general practitioners, nurses and educators need to know if a patient has used their prescribed medication or assess inspiratory flow and inhaler technique; and in patient self-management. The Hailie sensor is compatible only with the following TEVA MDI inhalers: ProAir® HFA & Albuterol Sulphate HFA. The Hailie sensor is not intended to indicate the remaining quantity of medication in an inhaler and does not include a dose counting function. The Hailie sensor is not intended to provide spirometry measurements.	Similar; the differences do not constitute a new intended for use or bring up new questions related to safety or effectiveness.

Attribute	**Subject:** **HeroTracker Sense® v1.2**	**Predicate:** **Hailie® Sensor NF0110** **K222247**	**Comparison**
	Advair 45 mcg / 21 mcg (120 count) Advair 115 mcg / 21 mcg (120 count) Advair 230 mcg / 21 mcg (120 count) Albuterol Sulfate (Prasco) 90 mcg (200 count) Fluticasone Propionate & Salmeterol 45 mcg / 21 mcg (120 count) Fluticasone Propionate & Salmeterol 115 mcg / 21 mcg (120 count) Fluticasone Propionate & Salmeterol 230 mcg / 21 mcg (120 count) Albuterol Sulfate (Lupin) 90 mcg (200 count)		
Design – Attachment to Medication Dispenser	Physically attached to dispenser without inhibiting patient use	Physically attached to dispenser without inhibiting patient use	Same
Principle of Operation	Attaches to the top of the medication canister and performs wireless uploading of usage history of the inhaler	Attaches to the top of the medication canister and performs wireless uploading of usage history of the inhaler	Same
Data Collection Technology	Records date and time of MDI usage and inhaler usage technique through sensors (force, acceleration, and airflow sensors).	Records date and time of MDI usage and inhaler usage technique through sensors (optical, induction coil, motion and flow sensors).	Similar; although the kind of sensors are not fully the same, the principle of operation is still the same.
Records Usage	Yes	Yes	Same
Dose Counter	No	No	Same
Patient Data Storage with Software	Yes	Yes	Same
Patient Data Report	Yes	Yes	Same

Attribute	**Subject:** **HeroTracker Sense® v1.2**	**Predicate:** **Hailie® Sensor NF0110** **K222247**	**Comparison**
Generation with Software			
Mobile Platforms	iOS 13 and higher version (13, 14, 15) Android 8 and higher version (8, 9, 10 11, 12).	iOS 9 and above Android 5.1 and above	Similar; both devices are available with recent versions of iOS and Android.
Required Off-the Shelf Hardware	Apple smartphones or devices with Bluetooth	Apple smartphones or devices with Bluetooth	Same
Wireless Technology Bluetooth	Bluetooth® 4.0: 2.40 - 2.48 GHz, 1.0 mW Low Energy	Bluetooth® 4.0: 2.40 - 2.48 GHz, 1.0 mW Low Energy	Same
Power Source	Lithium coin cell CR2032 non-rechargeable battery	Lithium Coin Cells Non-rechargeable Battery	Same
Battery Life / Service Life	1 year	1 year	Same
Case Material – Patient Contact by Intact Skin (Hands)	Cover: ABS Light diffuser: PC	Plastic cover	Similar; both devices are presented as a plastic external enclosure.
Electrical Safety	IEC 60601	IEC 60601	Same
Biocompatibility	ISO 10993-1	ISO 10993-1	Same
Sterility	Non-sterile	Non-sterile	Same

9. Non-Clinical Performance Data

To demonstrate safety and effectiveness of HTS and to show substantial equivalence to the predicate device, Voluntis completed the following non-clinical tests. Results confirm that the design inputs and performance specifications for the device are met. The HTS passed the testing in accordance with internal requirements, national standards, and international standards shown below, supporting its safety and effectiveness, and its substantial equivalence to the predicate device:

- Biocompatibility evaluation per ISO 10993-1 - Materials can be considered as biocompatible.
- Electrical safety testing per IEC 60601-1, IEC 60601-1-11, IEC 60601-1-6 – Passed
- Electromagnetic Disturbance (EMD) testing per IEC 60601-1-2 – Passed
- Software verification and validation per IEC 62304/FDA Guidance – The correct functionality for the HTS software release, for all software modules and for association with the compatible mobile app. to display the data was verified
- Biocompatibility evaluation of breathing gas pathways in healthcare applications per ISO 18562-1: The biological safety of the gas pathway is supported by a risk-based evaluation and is considered adequately addressed.

- Performance Testing – Device was verified to meet specifications and the correct functionality and compatibility for the HTS with the concerned MDI inhalers was verified
- Service Life – Supports 1 year service life
- Shelf-Life Testing – Supports 2 years shelf life
- Transportation testing per ASTM 4169 – confirmed the transport has no impact on device.

10. Clinical Performance Data

No clinical data was necessary to determine the substantial equivalence of this device.

11. Statement of Substantial Equivalence

The HTS has the same intended use as the predicate device and similar technological characteristics. The differences in technological characteristics do not raise new or different questions of safety and effectiveness. Based on the results of the risk assessment and all applicable testing, the HTS is determined to perform as intended during normal anticipated usage and is at least as safe, as effective, and performs as well as or better than the legally marketed predicate device and therefore can be determined to be substantially equivalent to the predicate device.