August 21, 2025

Tidal Medical Technologies LLC
% George Hattub
Medical Device Regulatory Affairs Specialist
Medicsense USA LLC
291 Hillside Avenue
Somerset, Massachusetts 02726

Re: K241152
Trade/Device Name: InSee
Regulation Number: 21 CFR 868.5690
Regulation Name: Incentive Spirometer
Regulatory Class: Class II
Product Code: BWF
Dated: January 28, 2025
Received: January 28, 2025

Dear George Hattub:

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,

Rachana Visaria -S

Rachana Visaria, 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.*

510(k) Number *(if known)*
K241152

Device Name
InSee

Indications for Use *(Describe)*
InSee is an accessory to the Vyaire Medical AirLife Incentive Spirometer (2500 mL and 4000 mL). InSee is indicated to flag and digitally record successful incentive spirometry attempts, use-related data and provide reminders to patients who are prescribed the Vyaire Medical AirLife Incentive Spirometer. It is intended to be used in a hospital environment by clinicians and patients.

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.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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# 510(k) Summary

Pursuant to CFR 807.92, the following 510(k) Summary is provided:


**1. (a) Submitter Address:**

George J. Hattub
Medicsense USA LLC
291 Hillside Avenue
Somerset, MA 02726
ghattub@comcast.net


**1. (b)** ***Manufacturer Address:*** Tidal Medical Technologies LLC
44 Montgomery Street, Suite 2-155
San Francisco, CA 94101

***Mfg. Phone:*** Tel.: 1-214-403-3662

***Contact Person:*** Mehdi Arani, CEO

***Date:*** August 21, 2025

**2.** ***Device & Classification Name:*** Incentive Spirometer (accessory)
Product Code BWF (21 CFR 868.5690)
InSee

**3.** ***Predicate Device:*** K781838: Incentive Spirometer (accessory)
Product Code BWF (21 CFR 868.5690
Calculator with Charger

***Reference Device:*** Air Incentive Spirometer: K791819 (parent device)

**4.** ***Description:*** InSee is an accessory to the Vyaire Medical AirLife incentive spirometer. InSee consists of a plastic enclosure which attaches to the base of the AirLife incentive spirometer and records the following parameters: the number of attempts above 250 ml (AT), the Target Volume (TA), the number of successful attempts (SU) and the maximum target volume (MX). The InSee device also provide patient reminders. This device is only compatible with the Vyaire AirLife Volumetric Incentive Spirometer- 2500 & 4000 mL. InSee is intended for use in the Hospital environment by clinicians and patients. The device is non-invasive, reusable, and intended for use by one patient at a time.

**5.** ***Indications for Use:***

InSee is an accessory to the Vyaire Medical AirLife Incentive Spirometer (2500 mL and 4000 mL). InSee is indicated to flag and digitally record successful incentive spirometry attempts, use-related data and provide reminders to patients who are prescribed the Vyaire Medical AirLife Incentive Spirometer. It is intended to be used in a hospital environment by clinicians and patients.

**6.** ***Comparison of Technological Characteristics:***

The table below depicts the similarities and differences to the predicate device.

| Feature/Characteristic | Subject Device InSee K241152 | Predicate Device CR Bard Calculator with Charger K781838 | Conclusion |
|---|---|---|---|
| Intended Use | InSee is an accessory to the Vyaire Medical AirLife Incentive Spirometer (2500 mL and 4000 mL). InSee is indicated to flag and digitally record successful incentive spirometry attempts, use-related data and provide reminders to patients who are prescribed the Vyaire Medical AirLife Incentive Spirometer. It is intended to be used in a hospital environment by clinicians and patients | Similar | Substantially equivalent |
| Product Code | BWF | BWF | Substantially equivalent |

| | | | |
|---|---|---|---|
| Parent Device | K791819 AirLife Spirometer | Similar | Substantially equivalent |
| Display | LED | Similar | Substantially equivalent |
| Control | Electronic microprocessor | Similar | Substantially equivalent |
| Reusable | Yes | Similar | Substantially equivalent |
| Construction | Thermoplastics | Similar | Substantially equivalent |
| Power | DC Lithium Battey/Rechargeable (1200 mAh) | Similar | Substantially equivalent |
| Reminder Intervals | OFF / 10 minutes / 20 minutes / 30 min / 60 minutes / 120 minutes. | Similar | Substantially equivalent |
| Dimensions | 6.24 x 3.34 x 1.14 inches | Similar | Substantially equivalent |
| Weight | 4.2 oz. | Similar | Substantially equivalent |
| Accessories | USB Charger, USB–C cable, User Manual | Similar | Substantially equivalent |
| Range of Target Volumes | 250mL-4000mL | Similar | Substantially equivalent |
| Display Parameters: Target Volumes (Ta) and Maximum Inspiratory Volumes (Mx) | All measurements are displayed as multiples of 250mL.<br><br>Range: 250mL-4000mL | Similar | Substantially equivalent |
| Display Parameters: Number of Attempts (At) and Number of Successes (Su) | All measurements are displayed as Whole Numbers (0,1,2,3…) | Similar | Substantially equivalent |
| Shelf Life | 2 years | Similar | Substantially equivalent |

7. ***Performance Evaluation:*** The performance evaluations of InSee, included testing for electrical safety, electromagnetic compatibility, cleaning and reprocessing validation, biocompatibility, software/cybersecurity, and a prospective clinical performance validation study. Collectively, these results confirmed InSee performs as intended.

1. IEC 60601-1 Medical Electrical Equipment Part 1: General requirements for basic safety and essential performance

2. IEC 60601-1-2:2014+A1:2020, Medical electrical General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility – Requirements and tests

3. 2015 FDA Guidance Document *Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling*, AAMI TIR12:2020, AAMI ST98:2022.

4. The biocompatibility of the patient contacting materials was demonstrated through conformance with ISO 10993-1:2018. Patient contacting materials were categorized as external skin contact for < 24hrs.

5. Content of Premarket Submissions for Device Software Functions Guidance Document. Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions Guidance Document. The Software Level of Concern was found to be Basic.

6. A prospective, IRB-approved performance validation study was conducted with 30 subjects using six production InSee devices attached to standard 4,000 mL adult incentive spirometers. Each subject completed eight tests across the full IS volume range (250–4,000 mL), generating 240 data points. In all cases, InSee accurately detected when the IS piston crossed the target mark, activated its audiovisual alert, and logged the inspiratory volume, achieving 100% agreement with blinded physician observation. The two-sided 95% confidence interval for accuracy was 98.5% to 100%, exceeding the prespecified criterion of ≥90%. Repeatability across devices and target volumes was also 100%. No adverse events, device deficiencies, protocol deviations, or missing data were reported. These findings confirm that the InSee device performs reliably and as intended under clinical use conditions.

**8.** ***Conclusion:*** The conclusions drawn from the testing conducted and comparisons made demonstrate that the subject device is as safe, as effective and performs as well as the predicate device.