June 18, 2026

Autonomous Healthcare, Inc.
% Paul Dryden
Consultant
ProMedic Consulting, LLC
131 Bay Pt. Dr. NE
St. Petersburg, Florida 33704

Re: DEN250025
Trade/Device Name: Syncron-E
Regulation Number: 21 CFR 868. 5896
Regulation Name: Ventilator waveform analysis software
Regulatory Class: Class II
Product Code: QVC
Dated: June 20, 2025
Received: June 23, 2025

Dear Paul Dryden:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your De Novo request for classification of the Syncron-E, a prescription device under 21 CFR Part 801.109 with the following indications for use:

> Syncron-E is a computer program (software) intended as an adjunctive aid for detecting evidence of ineffective efforts during exhalation and rest periods in previously recorded mechanical ventilation waveform data obtained while in volume control ventilation (VCV), pressure control ventilation (PCV), or pressure support ventilation (PSV) modes.
>
> Syncron-E is intended for respiratory therapists to analyze 30 to 60 minutes of previously recorded ventilator waveform data per analysis session, and a summarized analysis is displayed for their review. Use is restricted to files obtained from adult patients 22 years and older receiving invasive ventilation.
>
> The data is reviewed retrospectively and not to be used in time-sensitive scenarios.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the Syncron-E, and substantially equivalent devices of this generic type, into Class II under the generic name ventilator waveform analysis software.

FDA identifies this generic type of device as:

> **Ventilator waveform analysis software**. Ventilator waveform analysis software is a prescription device that uses software algorithms to analyze mechanical ventilation waveform data to detect, display, and summarize patient-ventilator interactions. The device provides results to healthcare providers as an aid to monitoring or clinical assessment.

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This law provides two options for De Novo classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. On December 13, 2016, the 21st Century Cures Act removed a requirement that a De Novo request be submitted within 30 days of receiving an NSE determination. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the Federal Register announcing the classification.

In accordance with section 513(f)(1) of the FD&C Act, FDA issued an order on February 10, 2023 automatically classifying the Syncron-E in class III, because it was not within a type of device which was introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, nor which was subsequently reclassified into class I or class II.

On June 23, 2025, FDA received your De Novo requesting classification of the Syncron-E. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the Syncron-E into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the De Novo request, FDA has determined that, for the previously stated indications for use, the Syncron-E can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in the following table:

Identified Risks to Health	Mitigation Measures
Delayed or incorrect patient management due to false positive, false negative, or erroneous detection from algorithm error or software malfunction	Clinical performance testing Software verification, validation, and hazard analysis Labeling
Incorrect interpretation of device output, including overreliance on algorithm or failure to correlate output with other clinical information	Human factors and usability testing Labeling
Incorrect output due to poor input data quality or unsupported ventilator characteristics	Software verification, validation, and hazard analysis Labeling
Incorrect output due to use error	Human factors and usability testing

	Software verification, validation, hazard analysis Labeling

Special Controls

In combination with the general controls of the FD&C Act, the ventilator waveform analysis software is subject to the following special controls:

(1) Clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. Testing must fulfill the following:
   (i) Device output must be compared against a clinically justified reference standard (e.g., ground truth established by expert adjudication);
   (ii) Agreement with the reference standard must be assessed across the clinically relevant range using performance metrics relevant to the device output;
   (iii) The clinical dataset must be representative of the intended use population and relevant clinical parameters (e.g., ventilation modes) and include all compatible ventilator models. Any data selection criteria or limitations must be fully described and justified; and
   (iv) Testing must use a dataset that is independent and distinct from the data used for training or development of the software algorithm(s).

(2) Software verification, validation, and hazard analysis must be provided. Software documentation must include:
   (i) Compatibility testing validating device performance with all compatible ventilators labeled to be compatible with the device;
   (ii) A description of the algorithm(s) used to analyze the data, including inputs and outputs, algorithm logic and related technical parameters, and criteria for excluding data from analysis; and
   (iii) Information regarding the dataset used to develop the algorithm(s), including the population studied and relevant clinical characteristics (ventilation modes and ventilator models).

(3) Human factors and usability testing must demonstrate the following:
   (i) The intended user(s) can correctly use the device and interpret the device output based solely on the directions for use and labeling; and
   (ii) Testing must be conducted in the intended use environment and inclusive of worst-case simulated use conditions to ensure compatibility with clinical workflows.

(4) Labeling must include:
   (i) A detailed summary of the device's technical parameters;
   (ii) A listing of compatible ventilator models and versions, ventilation modes, and associated settings;
   (iii) A summary of the clinical performance testing conducted with the device;
   (iv) A description of situations in which the device may fail or may not operate at its expected performance level (e.g., extreme ventilator settings or specific patient populations); and
   (v) A warning against overreliance on device output.

In addition, this is a prescription device and must comply with 21 CFR 801.109.

Although this letter refers to your product as a device, please be aware that some granted products may instead be combination products. If you have questions on whether your product is a combination product, contact CDRHProductJurisdiction@fda.hhs.gov.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the ventilator waveform analysis software they intend to market prior to marketing the device.

Please be advised that FDA's decision to grant this De Novo request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD&C 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 803) for devices or postmarketing safety reporting (21 CFR 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and if applicable, the electronic product radiation control provisions (Sections 531-542 of the FD&C Act; 21 CFR 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.

A notice announcing this classification order will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the De Novo request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

For comprehensive regulatory information about medical devices and radiation-emitting products, 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).

If you have any questions concerning the contents of the letter, please contact Sidra Mirza at 301-796-6471.

Sincerely,

JAMES J. LEE -S

James J. Lee, Ph.D.
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
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