July 14, 2026

Affirm Medical Technologies II, LLC
% Jenelle Mohan
Attorney, Regulatory Consultant
Jenelle N. Mohan, Esq
190 La Colina Dr.
Alamo, California 94507

Re: K261633
Trade/Device Name: VisuBreath
Regulation Number: 21 CFR 868.1400
Regulation Name: Carbon Dioxide Gas Analyzer
Regulatory Class: Class II
Product Code: CCK
Dated: May 17, 2026
Received: May 18, 2026

Dear Jenelle Mohan:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

Bradley Q. Quinn -S

Bradley Quinn
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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	

Please provide the device trade name(s).

VisuBreath

Please provide your Indications for Use below.

The VisuBreath is to provide a semi-quantitative visualization of the CO2 in the patient airway. It is an adjunct in patient assessment, to be used in conjunction with other methods to determine clinical signs and symptoms by or on the order of a physician. The VisuBreath has a visual indicator to visually detect the end of exhalation. For use up to 24 hours. For patients greater than 15 kg (33 lbs). Environment of Use - hospital, sub-acute, pre-hospital, transport. Prescription Use.

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☐ Children (2 years old to < 12 years old) ☐ Adolescents (12 years old to < 22 years old) ☐ Adults (22 years old and greater)

510(k) Summary
(As required by 21 CFR 807.92)
Prepared on 2026-07-14

510(k) Number: K261633

Affirm Medical Technologies II, LLC
246 Sea View Avenue
Piedmont, CA 94610
Tel: (415) 314-6257

Official Contact:	Brian Cain, MD
Proprietary or Trade Name:	VisuBreath
Common/Usual Name:	Carbon dioxide gas analyzer
Classification Name:	Analyzer, Gas, Carbon-Dioxide, Gaseous-Phase
Regulation Number:	21 CFR 868.1400
Product Code:	CCK
Predicate Device:	K133540 - FLOCAP – CCK

Device Description Summary:
VisuBreath is a sticker placed inside a patient mask, specifically designed to be used by healthcare providers for the continuous visualization of a patient's breathing, by colorimetrically responding to the presence of carbon dioxide in the patient's expired breath. The VisuBreath is a disposable, continuous color changing sticker that indicates a visual cue in the presence of carbon dioxide in expired breath. It allows the patient's breathing to be observed from a distance. The VisuBreath sticker is intended for use on non-intubated patients, including adult and pediatric patients. The device is an adjunct to supplement the real-time clinical assessment of the patient and is to be used in conjunction with other methods to determine clinical signs and symptoms.

Intended Use/Indications for Use:
The VisuBreath is to provide a semi-quantitative visualization of the CO2 in the patient airway. It is an adjunct in patient assessment, to be used in conjunction with other methods to determine clinical signs and symptoms by or on the order of a physician.
The VisuBreath has a visual indicator to visually detect the end of exhalation.

For use up to 24 hours.
For patients greater than 15kg (33 lbs).
Environment of use - hospital, sub-acute, pre-hospital, transport.
Prescription Use.

Predicate Device Comparison:

Indications for Use Comparison:

The Indications for Use for the VisuBreath are the same as for the predicate device: the Maxtec FLOCAP.

Technological Comparison:

The subject device, the VisuBreath, has similar intended use, operating principles and technological characteristics as the predicate device: the Maxtec FLOCAP.

Summary of Indication for Use, Intended Use and Principles of Operation:
The Indications for Use, duration of use, environment for use and patient populations are identical. Both devices share the same fundamental Indications for Use being a semi-quantitative visual indication of exhaled CO2. The principles of operation are the same; a colorimetric, pH sensitive dye is used for detecting the presence of CO2 and the amount. Where they differ is in the route of use. The predicate is used in-line airway, whereas the subject device is external to the airway and placed on the interior of a mask making its contact indirect with the patient airway. The contraindications for the subject device include that it is not to be used for patients who are mechanically ventilated and are not spontaneously breathing. The predicate also has limitations on how it can be used with those who are intubated and as such any difference between the contraindications does not affect the function, effectiveness or safety of the subject device. The differences in contraindications further emphasize that the subject device is less invasive it is to be used on those patients not needing to be mechanically ventilated.

Summary of Technology:
Material Equivalence: All materials used in the VisuBreath CO2 Detection Sticker are either identical or materially equivalent to those in the predicate device. The use of 3M medical-grade polyethylene films and acrylic adhesives introduces no new materials of unknown biocompatibility. Each constituent is well-established in FDA-cleared respiratory and skin-contact devices, and the indicator chemistry (m-cresol red) is widely used for CO2 colorimetric detection.

Technological Device Differences: The subject device's technological characteristics, where the CO2 in the expired breath creates a reversible chemical reaction on the pH sensitive media which changes the optical characteristics of that media, is similar to the predicate. There are a few differences between the predicate and subject device as follows:

The subject device changes in color from blue to yellow in the presence of CO2, whereas the predicate changes from purple to yellow in the presence of CO2. The resulting different colors to

show the presence of CO2 does not affect the device's safety or effectiveness. The predicate device registers multiple gradations of CO2 (0–1%, 1–2%, and >5%) to offer a visual scale, where as the subject device is binary in its CO_2 detection, providing a "yes/no" colorimetric response at a threshold of 2% CO_2, ("Yes" exhalation is detected or "No" exhalation detected). This design difference does not affect the safety or efficacy of the subject device for its intended purpose, because both devices rely on the same underlying colorimetric chemistry.

The noted difference in levels of CO2 indicated is due to the fact that the subject device is binary in its CO_2 detection, providing a "yes/no" colorimetric response at a threshold of 2% CO_2, ("Yes" exhalation is detected or "No" exhalation detected). The predicate device displays multiple gradations (0–1%, 1–2%, and >5%) to offer a visual scale. This design difference does not affect the safety or efficacy of the subject device for its intended purpose, confirmation of exhalation, because both devices rely on the same underlying colorimetric chemistry (pH change of sulfonephthalein dye in response to CO_2 hydration). The binary design aligns with the intended use of the VisuBreath CO_2 Detection Sticker: to provide a visual indication of exhaled CO_2 in spontaneously breathing patients using a face mask.

According to published data, the average concentration of CO_2 in human exhaled breath is between 4% and 5%, while ambient air contains approximately 0.04% CO_2 (Pleil JD, Ariel Geer Wallace M, Davis MD, Matty CM. "The physics of human breathing: flow, timing, volume, and pressure parameters for normal, on-demand, and ventilator respiration." J Breath Res. 2021 Sep 27;15(4):10.1088/1752-7163/ac2589. doi: 10.1088/1752-7163/ac2589. PMID: 34507310; PMCID PMC8672270). Because the subject device activates at approximately 2% CO_2, it operates well below the physiologic range of exhaled CO_2 and well above ambient levels.

Therefore, false-positive readings (color change without exhalation) and false-negative readings (failure to change color during exhalation) are not expected under any clinically relevant conditions. Bench testing confirmed that at flow rates up to 10 L/min, the transition from colorless to yellow occurs reliably and more rapidly with increasing flow due to CO_2 exchange dynamics. Across all tested flow rates, the device demonstrated consistent activation without any false-negative or false-positive events. Thus, while the predicate provides tiered quantitative gradations, the subject device provides a binary indication at a physiologically conservative threshold. This performance fully supports its intended use and raises no new questions of safety or efficacy relative to the predicate device.

The predicate device has a spinner/vane to visualize when there is expiratory flow. The subject device does not have a spinner/vane to visualize expiratory flow. The exclusion of a spinner/vane does not affect the subject device's performance as a semi-quantitative visualization of the presence of CO2 in the expired airstream as the visible color change indicates whether CO2 is present in the exhaled airstream.

The subject device is a sticker adhered directly to the interior of a clear oxygen mask as opposed to being attached to an endotracheal tube. The location of the device in the mask does not affect the function, effectiveness or safety of the subject device in comparison to the predicate.

Summary of Safety and Efficacy Considerations:
The subject device does not contact mucosal tissue or enter the breathing circuit. Therefore the risk profile is lower than the predicate. The materials in the subject device are identical or materially equivalent to the predicate and are limited to externally applied polymer films and adhesives that meet ISO 10993 criteria for skin contact. There is no energy source, moving parts or alteration of the inhalation pathway introduced by the subject device.

Biocompatibility and Performance Testing further supports the safety of the subject device. The materials utilized in the subject device are similar to the predicate and both have similar indirect patient contact. For the predicate, gas passes around the media and does not have to go through, similar to the subject detector sticker. The predicate's materials were evaluated and tested in the final, finished form and found to meet ISO 10993-1 testing for cytotoxicity, sensitization, and intracutaneous reactivity. The same tests have been performed on the subject device. In addition, we have performed gas emission VOC and PM2.5 testing on the predicate device and the device was found to meet ISO 18562. Through the bench testing, as well as the comparative specifications, he subject device was found to be similar to the predicate. Full performance testing was completed on the subject device, including testing for shelf-life, color change response time, leakage, anti-fog, packaging integrity, operational environment, usability, duration of use, burst pressure, oxygen reactivity and biocompatibility (mentioned above).

Efficacy: Both devices rely on the same chemical indicator reaction (pH shift of m-cresol red due to CO2 hydration). The sensing principle, color change visibility, and response time remain substantially equivalent for the intended semi-quantitative purpose. The open-air, interior mask mounted configuration does not alter the fundamental detection chemistry.

Substantial Equivalence Conclusion:
Testing and comparison to the predicate has demonstrated that the proposed subject device can be found substantially equivalent and any differences do not raise different issues of safety and effectiveness between the two devices. Design verification/validation testing demonstrates that the subject device has similar technological characteristics compared to the predicate Maxtec FLOCAP. The VisuBreath CO2 Detection Sticker utilizes equivalent materials, operates by the same detection mechanism and poses equal or lower patient risk relative to the predicate device.

Non-clinical Testing Summary & Conclusions:
The non-clinical testing was comprised of a variety of bench tests used to evaluate device performance, as well as a user validation test to evaluate usability. The tests were broken up into three categories. Preconditioning and packaging validation, performance and life cycle testing, and usability/human factors testing. The tests performed were as follows:

Preconditioning and packaging validation:
- Climatic conditioning, Vibration under compressive load, High altitude, Vibration without compressive load, Accelerated aging, and Gross leak detection.

Performance and life cycle testing:
Visual Inspections, Pouch peel strength, Detector sticker weight, Detector sticker performance over time, Detector sticker color change and visibility and Detector sticker oxygen reactivity.

Usability/human factors testing:
- Design Validation and Summative Usability study.

Test methods and pass/fail criteria were based on product performance specifications. The performance specifications were based largely on the predicate device; therefore, we believe that these tests will be conclusive in determining substantial equivalence to the predicate device in regard to the safety and efficacy of the device.

No clinical testing/data was generated in support of this submission, therefore this section is not applicable.

All test units passed all bench top performance tests as well as user validation testing. Based on these results we have determined that the subject device is as safe, as effective, and performs as well as or better than the predicate device.

Substantial Equivalence Comparison
Through performance testing, design and features, and non-clinical testing it has been demonstrated that the proposed device and predicate have been found to be substantially equivalent.