FDA CLASSIFICATION VERIFICATION

ARETE Capnoflow™ Oropharyngeal Airway

Revision:	Rev.A
Date:	March 10, 2026
Prepared By:	Jason Cianfrani, SME Medical Devices / JMEDTECH LLC
Prepared For:	Jason Keen, COO / ARETE John Brown, CEO / ARETE
Classification:	CONFIDENTIAL

Executive Summary

This report provides an independent regulatory assessment of the Capnoflow™ Oropharyngeal Airway, a passive, non-electronic, injection-molded medical device manufactured in India. The device functions as an oropharyngeal airway (OPA) with integrated design features that facilitate the use of external monitoring equipment: an airway portal and luer lock connectors for connection to external gas monitoring (capnography) hardware. The device itself contains no electronic components, sensors, software, or power source.

Capnoflow™ is properly classified as a Class I device under 21 CFR 868.5110, Product Code CAE (Oropharyngeal Airway), and is 510(k) Exempt. The device is a passive OPA whose accessory features (airway portal, luer lock gas sampling ports) are consistent with the existing landscape of commercially distributed specialty oropharyngeal airways such as the Guedel Airway, Ovassapian Airway, and Berman Airway, all of which incorporate design features to accommodate external instruments and monitors.

Device Description

Intended Use

The Capnoflow™ Oropharyngeal Airway is a device inserted into a patient's pharynx through the mouth to provide a patent airway. It is intended for use by trained healthcare professionals in clinical settings including anesthesiology, emergency medicine, and procedural sedation.

Device Characteristics

Characteristic	Description
Device Type	Passive, non-electronic oropharyngeal airway
Manufacturing Process	Injection molded
Sterility	Non-sterile
Airway Portal	Integrated airway port designed to allow passage of externally supplied instruments. No camera, optical elements, or electronics are part of the device.
Gas Monitoring Ports	Luer lock connectors for connection to external capnography / gas monitoring hardware. No sensors, analyzers, or electronics are part of the device.
Power Source	None — entirely passive device
Software	None
Patient Contact	Mucosal membrane (oropharynx) limited or prolonged contact duration

The Capnoflow™ is functionally analogous to existing commercially distributed specialty OPAs that incorporate channels, ports, or passages for external instruments. Established predicate-type devices in this category include the Guedel Airway, Ovassapian Fiberoptic Intubating Airway (designed for passage of a fiberoptic bronchoscope), and the Berman Airway (open-channel design for suctioning and scope passage). All of these devices are passive, non-electronic OPAs that facilitate the use of external instruments.

Regulatory Classification Verification

Based on the confirmed device description (passive OPA with accessory ports for external equipment), the classification is verified as follows:

Regulation Number	21 CFR 868.5110
FDA Definition	"An oropharyngeal airway is a device inserted into a patient's pharynx through the mouth to provide a patent airway."
Product Code	CAE
Device Class	Class I (General Controls)
510(k) Status	Exempt (subject to limitations in 21 CFR 868.9)
GMP Exempt?	NO — Full QMSR (21 CFR Part 820 / ISO 13485:2016) compliance required
Medical Specialty	Anesthesiology
Review Panel	Division of Anesthesia, Respiratory, and Sleep Devices (DHT1C)
Recognized Standards	ISO 5364:2016 (OPAs), ISO 11712:2023 (Supralaryngeal Airways)
Implanted Device?	No
Life-Sustaining/Supporting?	No

Verification Result

CONFIRMED. The Capnoflow™ Oropharyngeal Airway is properly classified as a Class I, 510(k) exempt device under 21 CFR 868.5110, Product Code CAE.

Disclaimer: *This report is provided as an independent regulatory assessment based on the device description and information provided by the client. It does not constitute legal advice. Final classification determinations rest with the FDA. A Pre-Submission (Q-Sub) meeting with the FDA is recommended if the client desires written confirmation of the regulatory pathway from the Agency.*

References:

CAE Product Code - FDA

21 CFR Part 868 -- Anesthesiology Devices

Federal Register :: Medical Devices; Reclassification and Exemption From Premarket Notification for Certain Classified Devices