Food and Drug Administration, HHS

§ 868.5110  Oropharyngeal airway.

(a) Identification. An oropharyngeal airway is a device inserted into a patient’s pharynx through the mouth to provide a patent airway.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in §868.9.


§ 868.5090  Emergency airway needle.

(a) Identification. An emergency airway needle is a device intended to puncture a patient’s cricothyroid membrane to provide an emergency airway during upper airway obstruction.

(b) Classification. Class II (performance standards).


Subparts D–E [Reserved]

§ 868.5110  Oropharyngeal airway.

(a) Identification. An oropharyngeal airway is a device inserted into a patient’s pharynx through the mouth to provide a patent airway.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in §868.9.